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No. 09- (1)

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

ROBERT CHAPMAN, LONN S. RIDER, QI HONG, DONALD KYLE AND ROBERT KUPPER,

Petitioners,

v.

MICHAEL LAWRENCE CASNER, JEN-SEN DUNG, ERNO M. KESKENY AND JIN LUO,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Two questions are presented:

1. How is the principle in *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 68 (1923), that a claim may be non-obvious when the inventor discovers a "source [of trouble or a problem] not before known" and then claims the resulting "application of the remedy," applied in light of *KSR International Co. v. Teleflex*, 550 U.S. 398 (2007)?

2. Does *Eibel* require recitation of the newly discovered source of the problem as claim limitations?

LIST OF PARTIES

The parties below are listed in the caption of this Petition:

> Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle and Robert Kupper (collectively, "Chapman"), Petitioners, Appellants and Senior Party in the Interference; and
>
> Michael Lawrence Casner, Jen-Sen Dung, Erno M. Keskeny and Jin Luo (collectively, "Casner"), Respondents, Cross-Appellants and Junior Party in the Interference.

The real party-in-interest for Chapman is Purdue Pharma L.P.

The real party-in-interest for Casner is Johnson-Matthey Public Limited Company.

CORPORATE DISCLOSURE

The parent corporations and publicly held companies that own ten percent or more of the partnership interests of Purdue L.P.:

NONE.

Upon information and belief, the parent corporations and publicly held companies that own ten percent or more of the stock of Johnson-Matthey Public Limited Company:

Johnson Matthey Inc.

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OPINION AND JUDGMENT BELOW

The opinion of the United States Court of Appeals for the Federal Circuit is unreported and is dated March 11, 2009. **Appendix A.** The Judgment of the United States Court of Appeals for the Federal Circuit is dated March 11, 2009 and issued as a mandate on June 22, 2009. **Appendix D.** A timely request for rehearing was denied on June 15, 2009. **Appendix C.**

STATEMENT OF JURISDICTION

This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1). This is a petition for a writ of certiorari from a judgment of the United States Court of Appeals for the Federal Circuit entered on March 11, 2009, and issued as a mandate on June 22, 2009, in *Chapman v. Casner*, Appeal Nos. 2008-1427, -1428 (Fed. Cir. March 11, 2009). **Appendix D.** ***See also*** **Appendix A.** A timely request for rehearing was denied on June 15, 2009. **Appendix C.**

STATUTORY PROVISION INVOLVED

Title 35 United States Code, Section 103(a)

> § 103. Conditions for patentability; non-obvious subject matter
>
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior

art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negatived by the manner in which the invention was made.[1]

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[1] Reference is made to Title 35 United States Code, Section 102 which reads:

§ 102. Conditions for patentability; novelty and loss of right to patent

A person shall be entitled to a patent unless—

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(Cont'd)

(Cont'd)

(e) the invention was described in

(1) an application for patent, published under section 122 (b), by another filed in the United States before the invention by the applicant for patent or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351 (a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or

(f) he did not himself invent the subject matter sought to be patented, or

(g) (1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or

(2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

STATEMENT OF THE CASE

The Court of Appeals for the Federal Circuit affirmed the order of the United States Patent and Trademark Office Board of Appeals and Interferences ("Board") that all of the claims of Chapman's U.S. patent application no. 11/391,897 (**Supplemental Appendix and Appendix E**) are unpatentable under 35 U.S.C. § 103(a) as obvious, not-withstanding that Chapman discovered the previously unknown source of a problem and then claimed the remedy. The Board's basis for federal jurisdiction was under 35 U.S.C. §§ 6(b) and 135(a). The Federal Circuit's basis for federal jurisdiction was under 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. § 141. **A4a.**

The Court of Appeals addressed the question of obviousness in a manner contrary to 35 U.S.C. § 103 and the precedents of this Court. The Federal Circuit's majority decision (**A2a-8a**) directly conflicts with this Court's holding in *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923) that a claim may be non-obvious when the inventor discovers a previously unknown source or cause of trouble or a problem and then claims the resulting application of the remedy. The Federal Circuit's decision also highlights a conflict between *Eibel* and this Court's decision in *KSR International Co. v. Teleflex*, 550 U.S. 398 (2007).

The wisdom of *Eibel* is of utmost importance today. The Court should note that extraordinary amounts of human and financial resources are expended by the pharmaceutical industry in discovering the causes and sources of medical problems such as diseases. Pharmaceutical inventions are not the result of simply

a need or the knowledge that a problem exists. If so, cancer and heart disease would have been cured decades ago. Real and inventive research is directed to the causes or sources of these known problems and diseases, and this research must be patentable if the industry is to continue its large investments. This Court should affirm the modern relevance of *Eibel* and direct that the discovery of the source of a problem is an important, non-obvious part of the inventive process.

Here, Chapman invented a method for preparing pharmaceutical oxycodone salts that have low levels of the potentially toxic impurity, 14-hydroxy.[2,3] **A22a-24a.**

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[2] The following abbreviated chemical terms are used:

8α = 8α,14-dihydroxy-7,8-dihydrocodeinone;
8β = 8β,14-dihydroxy-7,8-dihydrocodeinone;
14-hydroxy = 14-hydroxycodeinone; and
ABUK = α,β-unsaturated ketone.

[3] Chapman's sole independent claim reads as follows (**A21a**):

> 96. A process for preparing oxycodone or an oxycodone salt, which process comprises steps of:
> (a) preparing a mixture of oxycodone, solvent and an acid;
> (b) incubating the mixture under conditions suitable to promote reaction of 8,14-dihydroxy-7,8-dihydrocodeinone to 14-hydroxycodeinone; and subsequently
> (c) exposing the mixture to hydrogenation reagents under conditions sufficient for conversion of 14-hydroxycodeinone to oxycodone.

Chapman's invention was based upon their discovery of the previously unknown cause (the formation of 8α, a compound that Chapman first discovered and that converts to new 14-hydroxy) of a problem (the impurities in oxycodone salts that Chapman discovered were from the formation of new 14-hydroxy) that was misunderstood by the prior art. **A9a, 40a-41a**.

Oxycodone salt is a potent pain reliever (**A3a, 23a**) prepared by the following steps: (1) converting thebaine to 14-hydroxy; (2) converting the 14-hydroxy to oxycodone; and (3) adding dilute acid at room temperature to convert the oxycodone to its salt. **A3a-4a**. However, oxycodone salts prepared in this manner contain relatively high amounts of 14-hydroxy impurities. **A3a, 22a-23a**.

The prior art believed that the 14-hydroxy impurities in oxycodone salts were old 14-hydroxy that was created in step (1), was unreacted in step (2), and was carried over through step (3). **A9a, 25a-26a.** The prior art taught that step (1) only produced a single by-product, 8β, which was of no concern because, in step (3), 8β was converted to its benign, inert, stable salt, 8β salt. **A43a-47a**.

Chapman proved that the prior art understanding of how 14-hydroxy impurities appeared in oxycodone salt was wrong. Chapman discovered that the actual problem was not old, carry-over 14-hydroxy created in step (1); rather, it was 14-hydroxy that was newly formed in step (3) from a previously unknown source. **A3a-4a, 9a**. Chapman discovered that step (1) also produced a previously unknown compound, 8α, which, when salted

in step (3), was converted into new 14-hydroxy. **A3a-4a, 9a-10a**. This was why, no matter how thoroughly the prior art tried to remove old, left-over, excess 14-hydroxy that was formed in step (1), but which remained unconverted in step (2), pharmaceutical oxycodone salts still had unaccountable and unexpected higher levels of 14-hydroxy impurities.

Chapman remedied this problem by designing the claimed process: first, mixing the ingredients for salting oxycodone (Chapman step (a), which starts at the end of typical oxycodone production); second, letting the salting progress to convert all of the 8, 14-dihydroxy to something else (8β becoming its benign, inert, stable salt (**A5a**) and 8α becoming new 14-hydroxy (**A3a-5a, 9a-10a**)) (Chapman step (b)); and third, converting the new 14-hydroxy derived from 8α to oxycodone with little or no 14-hydroxy impurities remaining (Chapman step (c)). **A4a**.

The Federal Circuit majority erred by ignoring this Court's holding in *Eibel*.[4] The majority below looked to the obviousness of only a single step out of the sequence that Chapman claimed. **A6a-7a.** The Federal Circuit reasoned that Chapman's invention was obvious because the prior art disclosed that "8β, at least, will under certain reaction conditions form 14-hydroxy." **A8a**; ***see also*** **A6a-7a.**

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[4] The Court of Customs and Patent Appeals had followed this Court's holding in *Eibel*. *See, e.g.*, *In re Peehs*, 612 F.2d 1287, 1290 (C.C.P.A 1980); *In re Sponnoble*, 405 F.2d 578, 586 (C.C.P.A. 1969); **A11a-12a**.

This reasoning begs the question: why would anyone apply the foregoing reaction to a mixture of benign, inert, stable 8β salt and oxycodone salt in the absence of Chapman's discoveries that 8α was also there and formed new 14-hydroxy? The answer is that no one would and no one did. That is why *Eibel* should be followed even in light of this Court's discussion of obviousness in *KSR*.

The Federal Circuit majority relied upon the United States Food and Drug Administration's recognition that there was a need to eliminate impurities in oxycodone, as sufficient reason to combine elements of the prior art. **A7a-8a**. However, despite *KSR*, a mere need, regardless of the number of possible remedies, cannot serve as the reason to combine prior art elements if the application of the remedy is the result of a new discovery, as here.

There is a sharp conflict between this Court's decision in *Eibel* and this Court's decision in *KSR*. The application of *Eibel* here clearly results in the non-obviousness of Chapman's claims; however, the application of *KSR* can force obviousness. There was an industry need here, and when the source of the problem was discovered by Chapman, the remedy may have been to use well-known reactions. The fact remains, however, that, despite this need, the prior art did not disclose or suggest 8α, that 8α was also formed in step (1), or that step (3) converted 8α into new 14-hydroxy. These discoveries were Chapman's alone and were what led Chapman to the starting point and the subsequent steps in their claimed process.

Since one of ordinary skill at the time of Chapman's invention did not know that 8,14-dihydroxy was actually two compounds (the prior art 8β and Chapman's newly discovered 8α, each of which reacted differently under similar conditions), the skilled person would not have applied any prior knowledge about oxycodone production or about 8β to 8α. Furthermore, it would not have been even remotely obvious to try the foregoing reaction in the absence of Chapman's discovery that 8α existed. If one did not know that 8α existed, one could not have known to react it or how it reacted in comparison to 8β under oxycodone salting conditions. In fact, once one skilled in the art was told by Chapman of 8α's existence, it would have been a total surprise that it reacted entirely differently than 8β under the pertinent conditions.

Therefore, it was error for the Federal Circuit majority to have ignored this Court's holding in *Eibel* and to have concluded that Chapman's remedy to a problem with a previously unknown cause was obvious at the time of its invention. **A8a**. It is illogical for an industry need, with or without a finite number of remedies, to serve as a reason to combine references or to find obviousness when the source of the problem confronting the industry had previously been completely misunderstood. The discovery of the source of the problem is an innovation. Necessity can be the mother of a patentable invention, not its antithesis. *KSR* and *Eibel* must be reconciled.

As Judge Rader correctly stated in his dissent:

> Chapman, thus, was the first person to identify the true nature of the "leftover" 14-hydroxy problem and the first to solve it. . . . this important and innovative solution deserves a patent over the prior art.

A9a.

SUMMARY OF THE ARGUMENT

A. The Discovery of the Previously Unknown Source of a Known or Unknown Problem Must Still Indicate that the Remedy to that Problem Is Non-Obvious

Chapman's discovery of the previously unknown compound, 8α, as the source of problematic 14-hydroxy impurities in oxycodone salts is precisely the type of discovery that gave rise to a patent in *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 67-68 (1923). Eibel discovered the previously unknown source of a problem and then was granted a patent to the problem's remedy.

Eibel concerned a newsprint paper-making machine. Before Eibel entered the field, a standard paper-making machine could only run at about 500 feet/minute. Faster speeds resulted in defective paper. Inventor Eibel discovered that the defects were due to disturbances and ripples in the stock used to make the paper as the stock was forming (through the removal of water) on a traveling wire screen. He observed that the

wire screen was traveling much faster than the stock. This led him to conclude that, if the speed of the stock could be increased to approximately the speed of the wire, the disturbance and rippling in the stock would cease and the paper defects would disappear. Eibel proposed to increase the speed of the stock through the use of gravity, by inclining the wire. The use of an incline and gravity was known in the prior art to increase speed. However, no one had previously used an incline and gravity to increase stock speed to match the speed of the wire in paper production, because no one had previously understood the cause or source of the paper defects. Eibel made that discovery. The accused infringer alleged, *inter alia*, that the obvious application of the well-known principles of an incline and gravity made Eibel's invention unpatentable.

This Court confirmed the validity of Eibel's patent and held that although Eibel did not invent the paper-making machine, he did discover what caused the paper defects and used well known principles to fix it. Chief Justice Taft wrote:

> [O]ne essential part of Eibel's discovery was that the trouble causing the defective paper product under high machine speed was in the disturbance and ripples some ten feet from the discharge and that they were due to the unequal speeds of stock and wire at that point and could be removed by equalizing the speeds. The invention was not the mere use of a high or substantial pitch to remedy a known source of trouble. It was the discovery

> of *the source not before known* and the application of the remedy for which Eibel was entitled to be rewarded in his patent.

Eibel, 261 U.S. at 67-68 (emphasis added).

Chapman's invention, like Eibel's, is patentable. Chapman addressed a market need, as did Eibel, discovered the cause or source of a problem, as did Eibel, and applied a remedy, as did Eibel; and Chapman, as Eibel, is entitled to a patent covering that remedy.

It is irrelevant whether Chapman used known reaction schemes. They were never before applied to Chapman's reactants; nor were they ever before applied to remedy the previously unknown source (which Chapman first discovered) of the problem Chapman addressed. Chapman's discoveries and invention have allowed the industry to move forward and to make low ABUK oxycodone.

As Judge Rader aptly summarized the matter in his dissent:

> Chapman unexpectedly discovered that the stereoisomer 8α, when salted, creates additional 14-hydroxy. This additional 14-hydroxy can be isolated and hydrogenated to create additional oxycodone, containing much less of the 14-hydroxy that the FDA desired removed from oxycodone salt. Persons of ordinary skill in the art never discovered or appreciated the presence of 8α as the source of the additional 14-hydroxy. The

> prior art disclosed that 14-hydroxy was a carry-over from the oxidation of thebaine, resulting in leftover, unreacted 14-hydroxy in the oxycodone salt. "[T]he challenges of this inventive process would have prevented one of ordinary skill in this art from traversing the multiple obstacles to easily produce the invention in light of the evidence available at the time of the invention." *Ortho-McNeil*, 52 F.3d at 1365. Chapman, therefore, unexpectedly discovered the true source of the additional 14-hydroxy and solved the problem by removing the impurity from oxycodone salt. Because the prior art could not have intended or appreciated Chapman's discovery or solution, the invention deserves patent protection.

A14a.

The application of *KSR International Co. v. Teleflex*, 550 U.S. 398 (2007) gives a contrary result. This Court stated in *KSR* that:

> *any need or problem known* in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.

KSR, 550 U.S. at 420 (emphasis added).

However, this is in conflict with the facts and reasoning of this Court in *Eibel*. *See Eibel*, 261 U.S. at 68 ("It was the discovery of *the source not before known* and the application of the remedy for which Eibel was entitled to be rewarded in his patent." (emphasis added)). There was a need in the newspaper industry, and the problem was known to be defects in the paper. Eibel discovered the unknown source of the known problem and, then, claimed a remedy using known principles of physics to satisfy an industry need.

The Federal Circuit majority, in the case now before this Court, pointed out that "the Board noted that the FDA 'recognized that there was a need to eliminate impurities in oxycodone,' and then proceeded to walk through the prior art . . . ." **A7a-8a**. The alleged "need" was the Federal Circuit majority's invitation to combine elements of the prior art and directly resulted in the holding of obviousness of Chapman's claims. *See KSR*, 550 U.S. at 420 (any known need or problem can provide a reason to combine elements as claimed).[5]

However, in this case, as in *Eibel*, there was no reason to combine any prior art elements before the

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[5] It is also incongruous that in *KSR*, a need is a reason to combine prior art elements and make an invention obvious, but in *Graham*, 383 U.S. at 17, this Court found long-felt need to be objective evidence of non-obviousness. The speed at which an inventor makes his or her invention should not be a determining factor in the obviousness analysis. Speed of invention can be inventor-specific and dependent upon many different factors, including the skill of the inventor, the depth of his or her understanding of the problem or its source, the financial resources at his or her disposal, or even luck. None of these negates an inventor's innovation.

inventors' new discovery of the source of the problem. *KSR* is in conflict with *Eibel* on this point. The reasoning of *KSR* would make Eibel's invention unpatentable because the problem in *Eibel* was previously known and because there was an industry need. It was the previously unknown source of the problem that was Eibel's discovery and was the key to Eibel's claimed invention.

This conflict cannot be what this Court intended its reasoning in *KSR* to create. An examination of the facts of *KSR* is useful here. The patent-at-issue in *KSR* claimed a combination of a sensor and an adjustable pedal, where the pedal's position could be transmitted to a computer controlling the vehicle's throttle. The prior art, Asano, disclosed pedals that could be adjusted to change their position where one of the pedal's pivot points stayed fixed even when the pedal was adjusted. Appropriate electronic sensors and preferred sensor positions were also in the prior art, as were the facts that it was better to detect the position of the pedal position from within the pedal assembly rather than from within the engine and that it was better to place the sensor on a fixed part of the pedal assembly rather than on the pedal's footpad because of wire chaffing caused by the movement of a moveable sensor. The legal question was "whether a pedal designer of ordinary skill starting with Asano would have found it obvious to put the sensor on a fixed pivot point." *KSR*, 550 U.S. at 424-25.

This Court concluded that the *KSR* invention was obvious because a designer would have known to place the sensor on a non-moving point of the structure and

the most obvious suitable non-moving point was the pivot point. *KSR*, 550 U.S. at 425. The starting point, the problem, and the source of the problem were known at the time of the *KSR* invention; and the analysis could be performed without hindsight.

However, neither the starting point nor the source of the problem was known at the times of Eibel's or Chapman's inventions. Regarding the former, no one knew where to start. The prior art believed that 14-hydroxy was only created in step (1). No one knew that new 14-hydroxy was created in step (3), that 8α was its source, or that 8α reacted differently than 8β under the pertinent conditions. The source of the impurities, 8α, was Chapman's discovery alone, and absent the license of *KSR* to combine references based upon a "need" or a "known problem", only hindsight of Eibel's or Chapman's discovery could lead to a conclusion that their respective inventions were obvious. *See KSR*, 550 U.S. at 421 citing *Graham v. Deere*, 383 U.S. 1, 36 (1966) "(See *Graham*, 336 U.S. at 36 (warning against "temptation to read into the prior at the teachings of the invention in issue" and instructing courts to "'guard against slipping into the use of hindsight'" (quoting *Monroe Auto Equipment Co. v. Keckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412 (CA6 1964)))."

It is important for the promotion of the progress of science and useful arts, that this Court clarify that *KSR* does not abrogate its earlier holding in *Eibel*. *See Eibel*, 261 U.S. 45 at 68; *see also* U.S. CONSTITUTION, ARTICLE 1, SECTION 8. A claimed remedy may be non-obvious when any one of the starting point for the remedy, the

problem, or the source of the problem was unknown before it was discovered by the applicant for a patent claiming the remedy.

Accordingly, since Chapman discovered the previously unknown source of a problem, Chapman's claims are non-obvious.

B. *Eibel* Does not Require the Problem or Its Cause to Be Claim Limitations

Nothing in *Eibel* requires the problem or its cause to be limitations of the claimed remedy. However, the Federal Circuit majority required just that. The majority stated:

> Chapman argues that he was the first to recognize that additional 14-hydroxy is created from 8α during the reaction's salting step, and that the "new" 14-hydroxy can therefore yield additional oxycodone. Chapman purports to claim this method of eliminating the "new" 14-hydroxy in claim 96. The claim does not, however, differentiate between the 8α and 8β forms of 8,14-dihydroxy, nor does the claim language specifically disclose which conditions are "suitable" for promoting the desired reaction from 8, 14-dihydroxy to 14-hydroxy.

A4a.

Differentiation between the 8α and 8β forms of 8,14-dihydroxy and the conditions "suitable" for promoting the desired reaction from 8, 14-dihydroxy to 14-hydroxy are pertinent to Chapman's discovery of a new problem and its source. They are not necessary to claim a remedy to these problems and are not required claim limitations.

Eibel discovered that defects in paper were due to the fact that the wire screen on which stock formed paper traveled faster than the stock. This lead him to conclude that if the speed of the stock were increased to about the speed of the wire, disturbances and rippling in the stock would cease and the paper defects would disappear. The problem was disturbances and rippling in the stock, and this was caused by mismatched stock and wire speeds. The solution was to decline the wire and to move the suction boxes of the paper-making machine, neither of which was much of an invention absent the fact that these moves solved the problem. However, Eibel's claims 7 and 8 read:

> 7. A Fourdrinier machine having the paper-making wire declined from the breast-roll to the guide-roll, and the suction-boxes supported at corresponding declination, substantially as described.
>
> 8. A Fourdrinier machine having the paper-making wire declined from the breast-roll to the guide-roll, and the several suction-boxes arranged at different elevations, substantially as described.

Eibel, 261 U.S. at Prior History. Neither claim stated the problem or its source. However, this Court found that these claims were patentable.

Similarly, Chapman's claims as drafted (*i.e.*, absent the term 8α and species of suitable conditions) are patentable. Chapman's claims, even in their broadest interpretation, do not read on any single reference, and there was no reason to combine any references in the absence of Chapman's discovery. Therefore, Chapman's claims as written are non-obvious.

CONCLUSION

For all of the foregoing reasons, petitioners request that the Supreme Court grant this petition for a writ of certiorari and review this matter.

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DECIDED MARCH 11, 2009

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2008-1427, -1428
(Interference No. 105,553)

ROBERT CHAPMAN, LONN S. RIDER, QI HONG, DONALD KYLE, and ROBERT KUPPER,

Appellants,

v.

MICHAEL LAWRENCE CASNER, JEN-SEN DUNG, ERNO M. KESKENY, and JIN LUO,

Cross Appellants.

Appeals from the United States Patent and Trademark Office, Board of Patent Appeals and Interferences.

DECIDED: March 11, 2009

Before LOURIE, RADER, and PROST, Circuit Judges.

Opinion for the court filed by *Circuit Judge* PROST. Dissenting opinion filed by *Circuit Judge* RADER.

Appendix A

PROST, *Circuit Judge.*

Robert Chapman, Lonn Rider, Qi Hong, Donald Kyle, and Robert Kupper's ("Chapman's") U.S. Patent Application No. 11/391,897 ("the '897 application") and Michael Casner, Jen-Sen Dung, Erno Keskeny, and Jin Luo's ("Casner's") U.S. Patent No. 7,153,966 ("the '966 patent") both claim methods of preparing oxycodone that reduce the levels of a potentially toxic intermediate, 14-hydroxycodeinone. In Interference No. 105,553, the Board of Patent Appeals and Interferences ("the Board") granted Casner's motion seeking judgment that Chapman claims 96-118 were unpatentable under 35 U.S.C. § 103(a). Chapman appeals, asking us to hold claims 96-118 of the '897 application nonobvious. Casner maintains that those claims were obvious, but has also lodged a cross-appeal, arguing that if we reverse the Board's holdings as to the '897 application, we should reverse its holdings on the '966 patent and remand for a priority determination. For the reasons set forth below, we *affirm* the Board's obviousness determination.

I. BACKGROUND

The '897 application is entitled "Process for Preparing Oxycodone Hydrochloride Having Less Than 25 ppm 14-Hydroxycodeinone." The only independent claim at issue is claim 96, which recites:

> A process for preparing oxycodone or an oxycodone salt, which process comprises steps of:

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(a) preparing a mixture of oxycodone, solvent and an acid;

(b) incubating the mixture *under conditions suitable to promote reaction* of *8, 14-dihydroxy-7, 8-dihydrocodeinone* to 14-hydroxycodeinone; and subsequently

(c) exposing the mixture to hydrogenation reagents under conditions sufficient for conversion of 14-hydroxycodeinone to oxycodone.

J.A. 77 (emphases added).

Oxycodone is a synthetic analgesic opioid used to relieve pain. Typically, one prepares oxycodone by first oxidizing thebaine. This step converts thebaine into two types of compounds: 14-hydroxycodeinone ("14-hydroxy") and the 8, 14-dihydroxy-7, 8-dihydrocodeinones (collectively, "8, 14-dihydroxys"). The 14-hydroxy is converted via hydrogenation into oxycodone, which is then treated with acid during a final "salting" step to yield pharmaceutical grade oxycodone. Any 14-hydroxy remaining at the end of the reaction is problematic, as the compound is potentially toxic.

The 8, 14-dihydroxys created during the initial oxidation step are stereoisomers—there are two forms, designated "8α" and an "8β," that differ only by the relative orientation of a hydroxyl group. Chapman claims that prior to the '897 application, persons of

ordinary skill in the art did not know that 8α formed during the reaction. Instead, they believed that thebaine oxidized to form 14-hydroxy and 8β, and that any 14-hydroxy remaining at the end of the reaction was leftover, unreacted 14-hydroxy. In fact, during the salting step at least one of the 8, 14-dihydroxys reacts with acid to form "new" 14-hydroxy; this 14-hydroxy can then, of course, undergo hydrogenation to become additional oxycodone.

Chapman argues that he was the first to recognize that additional 14-hydroxy is created from 8α during the reaction's salting step, and that the "new" 14-hydroxy can therefore yield additional oxycodone. Chapman purports to claim this method of eliminating the "new" 14-hydroxy in claim 96. The claim does not, however, differentiate between the 8α and 8β forms of 8, 14-dihydroxy, nor does the claim language specifically disclose which conditions are "suitable" for promoting the desired reaction from 8, 14-dihydroxy to 14-hydroxy.

We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

II. DISCUSSION

Obviousness is a legal conclusion based on underlying findings of fact. *In re DBC*, 545 F.3d 1373, 1377 (Fed.Cir.2008). We review the Board's ultimate determination of obviousness de novo, while we review the Board's underlying factual findings for substantial evidence. *Id.*

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We first turn to Chapman's arguments. Chapman claims that prior to the '897 application, no one knew that 8α was formed during thebaine oxidation. Nor, according to Chapman, was it known that 8α could react with acid under certain "commercial conditions" to form additional 14-hydroxy. Chapman admits that the prior art disclosed 8β, but claims that "under commercial oxycodone production conditions," 8β converts into a benign salt, not into 14-hydroxy. In his view, the prior art would lead a person of ordinary skill in the art to believe that 8β must be treated with "stronger than commercially used" amounts of hydrochloric acid before it converts to 14-hydroxy.

Casner states that Chapman never claimed 8α as crucial to the invention before the Board; in other words, Chapman never tried to distinguish the prior art based on stereochemistry. Casner likewise argues that Chapman waived any "commercial conditions" limitation. Chapman responds that both issues were raised, although the stereochemistry argument is emphasized on appeal because Casner did not produce the "Proksa" reference (upon which the Board relied) until its response, leaving Chapman little opportunity to analyze and respond to the specific issues raised by that reference. Chapman also argues that since the Board identified a "commercial need" for reduced levels of 14-hydroxy, and found that a person of skill in the art would work in the "highly competitive pharmaceutical industry," the Board understood that commercial conditions were at issue.

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Chapman does not direct us to specific arguments in submissions to the Board where counsel pursued the claim that commercial conditions were necessary; nor has Chapman clarified which conditions would qualify as "commercial conditions." Similarly, although 8α is identified in some of the '897 application's figures, and Chapman's expert made references to stereoisomers in reviewing the prior art, Chapman has not identified any statement before the Board that explicitly differentiated between the invention and the prior art based on stereochemistry.

Regardless, we need not resolve the waiver issue definitively. Chapman maintains, and we agree, that "[t]he term '8, 14-dihydroxy' properly includes 8α, but there is no reason for that term to be limited to that isomer in Chapman's claims. The term 'conditions' properly includes commercial conditions, but there is no reason to limit that term to commercial conditions in Chapman's claims." Appellant's Reply Br. 27. Further, the '897 application states: "The term 8, 14-dihydroxy-7, 8-dihydrocodeinone includes either 8α, 14-dihydroxy-7, 8-dihydrocodeinone; or 8β, 14-dihydroxy-7, 8-dihydrocodeinone or can include a mixture of both compounds." '897 application ¶ 0043.

Thus, claim 96 merely requires one to incubate the mixture "under conditions suitable to promote reaction" of 8, 14-dihydroxy to 14-hydroxy. Therefore, prior art references that disclose either the 8α or 8β form of 8, 14-dihydroxy converting to 14-hydroxy, or disclose any reaction condition (whether "commercial" or not) that

promotes the conversion of 8α or 8β to 14-hydroxy, may render the claim obvious. *See In re May*, 574 F.2d 1082, 1088-89 (C.C.P.A.1978) ("[The reference] expressly discloses . . . a species within the genus of claim 1. Therefore, [the reference] is a technical anticipation of claim 1. Appellants' assertions to the contrary notwithstanding, this finding does not constitute a new ground of rejection; lack of novelty is the epitome of obviousness."); *cf. Medichem, S.A. v. Rolabo, S.L.*, 353 F.3d 928, 934-35 (Fed. Cir. 2003) (concluding that first step of an interference-in-fact inquiry was satisfied where two method claims had a genus/species relationship, since " '[i]t is . . . an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is "anticipated" if one of them is in the prior art.' ") (quoting *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782 (Fed.Cir.1985)); *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 971 (Fed. Cir. 2001) (in context of an obviousness-type double patenting analysis, noting that "[t]he only other difference between [the two method claims] is that the former is directed to humans while the latter is directed to animals," and "[o]ur case law firmly establishes that a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim.").

The Board found that the prior art discloses methods under which at least one 8, 14-dihydroxy reacts to yield 14-hydroxy under certain conditions. Specifically, the Board noted that the FDA "recognized that there was a need to eliminate impurities in oxycodone," and

then proceeded to walk through the prior art, which disclosed: that both 14-hydroxy and 8, 14-dihydroxy were known impurities during the thebaine oxidation reaction; that treatment of 8, 14-dihydroxy with hydrochloric acid converts 8, 14-dihydroxy into 14-hydroxy under certain reaction conditions; that one of skill in the art would be able to identify those conditions; and that 14-hydroxy may be removed from oxycodone via hydrogenation.

As mentioned, claim 96 would have been obvious if properly-combinable references disclosed conditions suitable to promote reaction of 8, 14-dihydroxy to 14-hydroxy. The prior art references here do just that: they indicate that 8β, at least, will under certain reaction conditions form 14-hydroxy. Given that claims directed to the genus (methods for eliminating 8, 14-dihydroxys) can be anticipated or rendered obvious by references disclosing the species (methods for eliminating either the 8α or 8β form of 8, 14-dihydroxy), we agree with the Board that the method described in claim 96 would have been obvious. As a result, we need not address Casner's cross appeal.

III. CONCLUSION

For the reasons detailed above, we affirm the Board's decision to reject claims 96-118 of the '897 application under 35 U.S.C. § 103(a).

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RADER, *Circuit Judge*, dissenting.

The Food and Drug Administration seeks the removal of impurities such as 14-hydroxy from the pain medicine oxycodone salt. During research on oxycodone, Chapman discovered that oxidation of thebaine creates the stereoisomer 8α, which in turn creates additional 14-hydroxy during formulation of this important pharmaceutical. Until this discovery, this field of art believed that the original oxidation step created the additional 14-hydroxy impurity. After discovering 8α, Chapman learned to isolate and hydrogenate the additional 14-hydroxy to eliminate most of these impurities. Chapman, thus, was the first person to identify the true nature of the "leftover" 14-hydroxy problem and the first to solve it. Because this important and innovative solution deserves a patent over the prior art, I would reverse the Board.

Chapman's invention calls to mind the Supreme Court's resolution of *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 43 S.Ct. 322, 67 L.Ed. 523 (1923). In *Eibel*, the primary distinction of the invention over the prior art was discovery of the problem in that discipline. *Id.* at 67-68, 43 S.Ct. 322. Eibel discovered that unequal speeds of stock and wire produced a defective paper product under high machine speeds. *Id.* The variance in paper speed created disturbances and ripples some ten feet from the discharge. *Id.* With the problem defined, Eibel easily prescribed the solution by elevating one end of the paper

feed to equalize the speeds of the wire and the paper stock by gravity. *Id.* at 64, 43 S.Ct. 322.

In this case, Chapman discovered that the salting of stereoisomer 8α, not the oxidation of thebaine, created the additional 14-hydroxy impurity in oxycodone salt. He solved this problem by isolating and hydrogenating the 14-hydroxy to form additional oxycodone. Chapman's invention was not the mere use of a known technique to remedy a known source of trouble, but was, as Chief Justice Taft stated, "the discovery of the source not before known and the application of the remedy" for which he seeks reward of the grant of a patent. *Id.* at 68, 43 S.Ct. 322.

Similarly, in *In re Conover,* Conover discovered a solution to the problem of connecting a rod to an outboard motor engine containing compact, anti-friction roller bearings. 49 C.C.P.A. 1205, 304 F.2d 680, 681 (1962). A phenomenon known as "galling" could destroy the bearings at unpredictable times by heating of the roller elements. *Id.* at 681-82. To overcome this "galling," Conover put a non-galling material, such as silver, on the end faces of the connecting rod bearings. *Id.* at 682. Citing the rationale of *Eibel,* the Court of Customs and Patent Appeals ("CCPA") found that the differences between Conover's patent application and the prior art were such that "the subject matter as a whole," *i.e.,* (a) "the discovery of the cause of the bearing failures" and (b) "its elimination by the claimed plating of . . . the contacting areas of the face portions of the connecting rods and the crank cheeks, were not obvious from the

prior art at the time the invention was made to a person having ordinary skill in this art." *Id.* at 684.

In *In re Sponnoble,* the pharmaceutical industry faced the problem of unwanted moisture leakage between liquid and solid compartments in vials. 56 C.C.P.A. 823, 405 F.2d 578, 586 (1969). Sponnoble discovered that the cause of this leakage was the passage of moisture through, rather than around, the center plug of the vial. *Id.* He solved the problem by fabricating a center seal plug of butyl rubber with a silicone coating. *Id.* The CCPA found, "a patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the 'subject matter as a whole' which should always be considered in determining the obviousness of an invention under 35 USC 103." *Id.* at 585. In resolving the issue of obviousness, the court stated, "The crux of the matter . . . is the discovery by appellant that passage through the center plug was a major cause of moisture transmission." *Id.* at 586. The court reasoned that "[t]he question here is whether the prior art recognized the cause of the problem," which it did not. *Id.*

The CCPA in *In re Peehs* found that Peehs had represented to the Patent and Trademark Office that up until the time of the claimed invention, "the nuclear [power] industry faced the problem of undesirable stressing of fuel rod claddings in gas-cooled nuclear reactors." 612 F.2d 1287, 1290 (C.C.P.A.1980). Peehs discovered that "the cause of this stressing was sticking

between the metal surfaces of the claddings and the contact elements of the spacer grids." *Id.* He solved this problem by "roughening one of the contact surfaces." *Id.* Thus, as in *Eibel*, *Conover*, and *Sponnoble*, "the crux of the matter is the discovery by appellants of the cause of a problem, and the determinative question is whether that cause would have been recognized by one of ordinary skill in the art at the time the invention was made." *Id.*

In reversing the Board's holding of obviousness, the CCPA found "no support for the conclusion that those of ordinary skill in the art would have recognized that sticking between the fuel rod claddings and the spacer grid contact elements caused the stressing of the claddings." *Id.* The court also found that " '[where] there is no evidence of record that a person of ordinary skill in the art at the time of [an applicant's] invention would have expected [a problem]', *e.g.*, sticking, 'to exist at all, it is not proper to conclude that [an invention]', *e.g.*, roughening one of the contact surfaces, 'which solves this problem, . . . would have been obvious to that hypothetical person of ordinary skill in the art.' " *Id.* (citing *In re Nomiya*, 509 F.2d 566, 572 (C.C.P.A.1975)).

The Supreme Court in *KSR International Co. v. Teleflex Inc.* recently held that "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product

not of innovation but of ordinary skill and common sense." 127 S.Ct. 1727, 1742 (2007). This case, as are *Eibel*, *Conover*, *Sponnoble*, and *Peehs*, is distinguished from *KSR* because there were no "finite number of identified, predictable solutions" that were used to discover the source of and solution to the problems. *Id.* No persons of ordinary skill in the art knew of the existence of 8α before Chapman and, in fact, were trying to solve the problem of removing excess 14-hydroxy impurities from oxycodone salt by other means. Because no other persons had discovered and solved this problem as Chapman did, his invention is the product of innovation and not of "ordinary skill and common sense." *Id.*

Following *KSR*, this court in 2008 in *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, found an invention worthy of a patent when a researcher in his search for a new antidiabetic drug, accidentally discovered topiramate. 520 F.3d 1358 (Fed. Cir. 2008). Topiramate is a reaction intermediate that has powerful anticonvulsant properties marketed by Ortho-McNeil as TOPOMAX® for the treatment of epilepsy. *Id.* at 1360. This court attached particular importance to the objective criteria of nonobviousness, including the powerful, unexpected results of topiramate (*i.e.*, anticonvulsive activity), skepticism of experts, copying, and commercial success. *Id.* at 1365. "As this court has repeatedly explained, this evidence is not just a cumulative or confirmatory part of the obviousness calculus but constitutes independent evidence of nonobviousness." *Id.* (citing *Catalina Lighting, Inc. v.*

Lamps Plus, Inc., 295 F.3d 1277, 1288 (Fed.Cir.2002) ("Objective indicia may often be the most probative and cogent evidence of nonobviousness in the record.")).

Chapman unexpectedly discovered that the stereoisomer 8α, when salted, creates additional 14-hydroxy. This additional 14-hydroxy can be isolated and hydrogenated to create additional oxycodone, containing much less of the 14-hydroxy impurities that the FDA desired removed from oxycodone salt. Persons of ordinary skill in the art never discovered or appreciated the presence of 8α as the source of the additional 14-hydroxy. The prior art disclosed that 14-hydroxy was a carry-over from the oxidation of thebaine, resulting in leftover, unreacted 14-hydroxy in the oxycodone salt. "[T]he challenges of this inventive process would have prevented one of ordinary skill in this art from traversing the multiple obstacles to easily produce the invention in light of the evidence available at the time of invention." *Ortho-McNeil*, 520 F.3d at 1365. Chapman, therefore, unexpectedly discovered the true source of the additional 14-hydroxy and solved the problem by removing the impurity from oxycodone salt. Because the prior art could not have intended or appreciated Chapman's discovery or solution, this invention deserves patent protection.

For the foregoing reasons, I respectfully dissent.

APPENDIX B — MEMORANDUM OPINION AND ORDER OF THE UNITED STATES PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES ENTERED MARCH 13, 2008

UNITED STATES PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

Patent Interference 105,553 McK
Technology Center 1600

MICHAEL LAWRENCE **CASNER**, JEN-SEN DUNG, ERNO M. KESKENY and JIN LUO,

Patent 7,153,966 B2,
Junior Party,

v.

ROBERT **CHAPMAN**, LONN S. RIDER, QI HONG, DONALD KYLE and ROBERT KUPPER,

Application 11/391,897,
Senior Party,

Before: FRED E. McKELVEY, *Senior Administrative Patent Judge*, and RICHARD TORCZON and MICHAEL P. TIERNEY, *Administrative Patent Judges*.

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McKELVEY, *Senior Administrative Patent Judge.*

MEMORANDUM OPINION and ORDER
Decisions on Motions

A. Statement of the case

The interference is before a motions panel for consideration of non-priority motions filed by the parties.

Chapman Motion 1

Chapman Motions 1-2 seeks an earlier constructive reduction to practice. Paper 24.

Casner timely filed Casner Oppositions 1-2. Paper 42.

Chapman timely filed Chapman Replies 1-2. Paper 59.

Chapman Motion 1 is dismissed as moot.

Casner Motion 1

Casner Motion 1 seeks judgment based on no interference-in-fact. Paper 28.

Chapman timely filed Chapman Opposition 1. Paper 44.

Casner timely filed Casner Reply 1. Paper 53.

Chapman Motion 1 is denied.

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Casner Motion 2

Casner Motions 2-5 seeks to deny earlier constructive reductions to practice accorded to Chapman when the interference was declared. Paper 29.

Chapman timely filed Chapman Oppositions 2-5. Paper 45.

Casner timely filed Casner Replies 2-5. Paper 54. Casner Motions 2-5 is dismissed as moot.

Casner Motions 6-7

Casner Motions 6-7 seeks judgment based on an alleged lack of written description on the part of Chapman. Paper 30.

Chapman timely filed Chapman Oppositions 6-7. Paper 46.

Casner timely filed Casner Replies 6-7. Paper 55.

Casner Motions 6-7 is denied.

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Casner Motions 9-10

Casner Motions 9-10 seeks judgment based on alleged unpatentability of the Chapman claims. Paper 32.

Chapman timely filed Chapman Oppositions 9-10. Paper 48.

Casner timely filed Casner Replies 9-10. Paper 57.

Casner Motions 9-10 is granted. We also hold that involved Casner claims 1-12 are unpatentable under 35 U.S.C. § 103.

Order of deciding motions

The rules authorize the Board to take up motions for decisions in any order. 37 C.F.R. § 41.125(a) (2007).

First, we elect to consider first Casner Motions 9-10 which urges unpatentability under 35 U.S.C. § 103.

We do so because we believe the case is more easily understood by discussing the evidence relevant to that motion.

Second, we then take up Casner Motion 1 urging no interference-in-fact.

Third, we take up Casner Motions 6-7 urging unpatentability for lack of written description and lack of enablement.

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In view of the disposition of Casner Motions 9-10, Casner Motion 1 and Casner Motions 6-7, we do not believe it necessary to consider the remaining motions.

The interference—parties

The interference involves junior party patentee Casner versus senior party applicant Chapman.

Junior party patentee Casner is involved on the basis of Casner patent 7,153,966 B2 issued 26 December 2006, which is based on application 11/234,627 filed 23 September 2005.

The Casner real party in interest is Johnson Matthey Public Limited Company. Paper 6.

Casner has been accorded earlier constructive reductions to practice (*i.e.*, benefit for the purpose of priority) based on the following applications:

British patent application 04-21149.6 filed 23 September 2004

Senior party applicant Chapman is involved on the basis of Chapman application 11/391,897, filed 29 March 2006.

The Chapman real party in interest is Purdue Pharma L.P. Paper 9.

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Chapman has been accorded earlier constructive reductions to practice based on the following applications:

Application 11/093,626,
filed 30 March 2005,
now U.S. Patent 7,129,248,
issued 31 October 2006

Provisional application 60/620,072,
filed 18 October 2004

Provisional application 60/601,534,
filed 13 August 2004

Provisional application 60/557,492,
filed 30 March 2004

The interference—subject matter (i.e., count)

A process according to claim 1 of Casner Patent 7,153,966 B2 or a process according to claim 96 of Chapman application 11/391,897.

Claim 1 of Casner reads:

> A process for preparing oxycodone or an oxycodone salt, comprising the steps of:
>
> a) preparing a mixture comprising oxycodone and a solvent, adjusting the pH of the mixture to less than 6

and heating the mixture at the temperature of at least 55°C for a period of at least 1 hour; and subsequently

b) exposing the mixture to hydrogenation reagents for a period of at least 1 hour.

Claim 96 of Chapman reads:

A process for preparing oxycodone or an oxycodone salt, which process comprises [the] steps of:

(a) preparing a mixture of oxycodone, solvent and an acid;

(b) incubating the mixture under conditions suitable to promote reaction of 8,14-dihydroxy-7,8-dihydrocodeinone to 14-hydroxycodeinone; and subsequently

(c) exposing the mixture to hydrogenation reagents under conditions sufficient for conversion of 14-hydroxycodeinone to oxycodone.

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The claims of the parties are:

Casner: 1-12

Chapman: 96-118

The claims that correspond to Count 1 are:

Casner: 1-12

Chapman: 96-118

The claims that do not correspond to Count 1 are:

Casner: None

Chapman: None

B. Findings of fact

The following findings of fact are believed to be supported by a preponderance of the evidence. To the extent that a finding of fact is a conclusion of law, it may be treated as such. Additional findings as necessary may appear in the Discussion portions of the opinion.

The invention

The invention relates to a method for making oxycodone using a hydrogenation step. An object of the method is the formation of oxycodone having low levels (*i.e.*, a few parts per million (ppm)) of α,β-unsaturated

ketone impurities. Ex 2001, col. 1:65 to col. 2:9; Ex 2002, page 1, ¶¶ 0002 & 0014. *See also* Ex 1028, ¶ 4.

Oxycodone is known to be useful in pharmaceutical products as an analgesic. Ex 2001, col. 3:42-45; Ex 2002, page 1, ¶ 0003.

Oxycodone has a ring structure.

The ring-numbering system used by the parties appears to be the Chemical Abstracts numbering system, an example of which appears in Chin, U.S. Patent 6,177,567 B1, col. 2:15-20.

Specifically, oxycodone has the chemical structure shown in Figure 1. Ex 1008, page 4, ¶ 15 (ring positions 7, 8 and 14 are hand-labeled).

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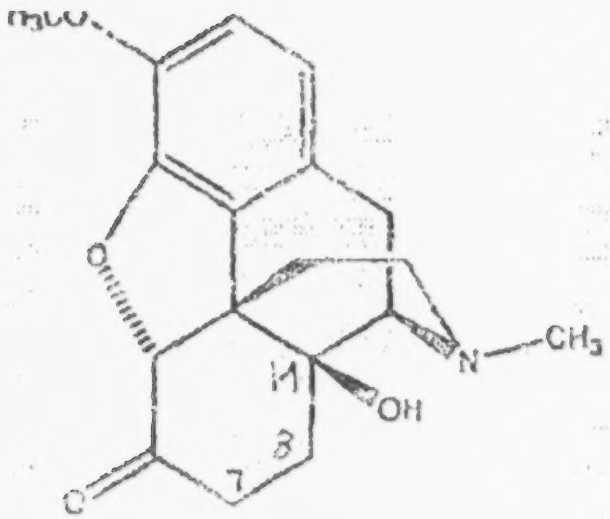

oxycodone

Figure 1—Structural formula of oxycodone

Important features of the structure are (1) a hydroxyl group [—OH] attached at the 14-position and (2) the absence of unsaturation [*i.e.*, a double bond (—CH=CH—)] between the 7- and 8-positions.

The principal α,β-unsaturated ketone impurity, which the invention seeks to minimize, if not remove, is 14-hydroxycodeinone.

14-hydroxycodeinone has the chemical structure shown in Figure 2. Ex 2001, col. 1:40 (formula on the right); Ex 2002, page 070, Fig. 2 (ring positions 7, 8 and 14 hand-labeled).

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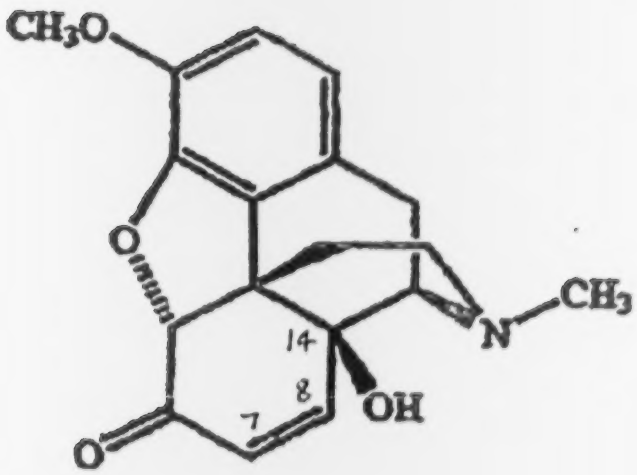

Figure 2—Structural formula of 14-hydroxycodeinone

An important feature of the structure is the double bond between the 7- and 8-positions.

The double bond results in an α,β-unsaturated compound with α being the 7-position and β being the 8-position.

Oxycodone can be manufactured from a compound known as "thebaine" by a known process disclosed in U.S. Patent 6,090,943. Ex 2001, col. 1:31-33.

The involved Chapman application explains the overall process in the following words. Ex 2002, page 006, ¶ 0013.

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During the oxidation of thebaine to give 14-hydroxycodeinone, several overoxidized products are formed including 8,14-dihydroxy-7,8-dihydrocodeinone. In the production of oxycodone free base from 14-hydroxycodeinone, the 8,14-dihydroxy-7,8-dihydrocodeinone is carried through the process. During conversion of the oxycodone free base to oxycodone hydrochloride, the impurity [i.e., 8,14-dihydroxy-7,8-dihydrocodeinone] undergoes acid-catalyzed dehydration and is converted into 14-hydroxycodeinone. Thus, 14-hydroxycodeinone can be present in the final oxycodone hydrochloride composition.

Thebaine has the structural formula shown in Figure 3.

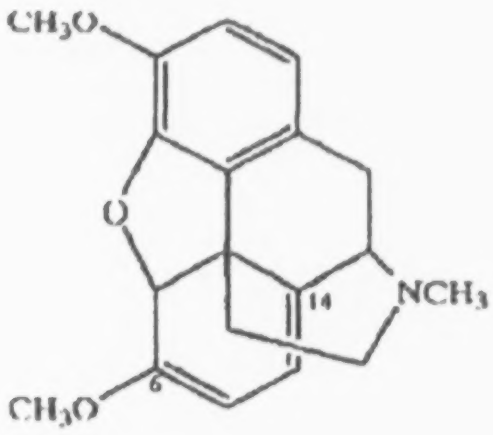

Figure 3—Structural formula of thebaine

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The structural formula of thebaine was copied from U.S. Patent 6,090,943, col. 1:20, the patent mentioned in the involved Casner patent. Ex 2001, col. 1:31-33.

By oxidation, Chapman means a reaction which results in 14-hydroxycodeinone by (1) addition of a hydroxy group (—OH) at the 14-position, (2) conversion of the methoxy group [—OCH_3] at the 6-position to a keto group [=O], and (3) replacing the two double bonds between the 6- and 7- and 8- and 14-positions with a single double bond between the 7- and 8-positions. Compare Figure 3 (thebaine) with Figure 2 (14-hydroxycodeinone) and *see* Ex 1028, page 5, ¶ 13.

By overoxidized, Chapman means a reaction which results in (1) addition of a hydroxyl group (—OH) at both the 8- and 14-positions along with (2) elimination of a double bond between the 8-position and the 14-position resulting in formation of 8,14-dihydroxy-7,8-dihydrocodeinone.

8*a*,14-dihydroxy-7,8-dihydrocodeinone has the structural formula shown in Figure 4 (ring positions 7, 8 and 14 and two methyl groups (—CH_3) are hand-labeled).

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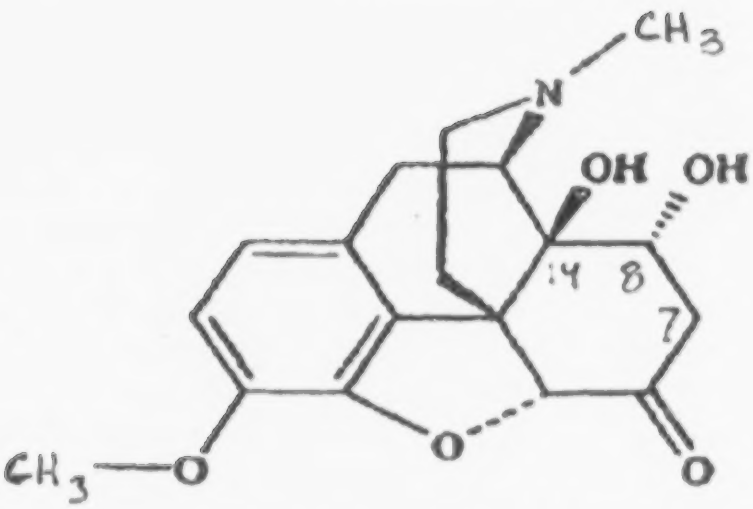

Figure 4-Structure of 8a,14-dihydroxy-7,8-dihydrocodeinone

As shown in Figure 4, there is a hydroxyl group at both the 8- and 14-positions and there is no double bond between the 7- and 8-positions. The chemical structure was reproduced from Ex 2002, page 070, Fig. 2.

Casner process

The Casner invention provides a process for preparing oxycodone or an oxycodone salt having low levels of impurities, comprising the steps of:

(a) preparing a mixture comprising oxycodone and a solvent and adjusting the pH of the mixture to less than 6; and subsequently

> (b) exposing the mixture to hydrogenation reagents for a period of at least 1 hour. Ex 2001, col. 2:7-15.

According to Casner, the process is said to surprisingly provide oxycodone with low levels of α,β-unsaturated ketone impurities, *i.e.*, 14-hydroxycodeinone at less than 15 ppm. Ex 2001, col. 2:16-19.

Further according to Casner, in order to achieve low levels of 14-hydroxycodeinone, the pH must be adjusted by adding an acid before the hydrogenation step. Ex 2001, col. 2:16-21.

More specifically, Casner discloses that suitably the mixture is heated after the pH of the mixture is adjusted, so that the process comprises the steps of:

> (a) preparing a mixture comprising oxycodone and a solvent, adjusting the pH of the mixture to less than 6 and heating the mixture at the temperature of at least 55° C. for a period of at least 1 hour; and subsequently
>
> (b) exposing the mixture to hydrogenation reagents for a period of at least 1 hour. Ex 2001, col. 2:21-29.

The process is said to provide oxycodone with very low levels of α,β-unsaturated ketone impurities, *i.e.*, 14-hydroxycodeinone at less than 5 ppm.

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Chapman process

One object of Chapman is a process for reducing the 14-hydroxycodeinone in an oxycodone hydrochloride composition to an amount of less than about 5 ppm. Ex 2002, pages 0006-0007, ¶ 0016.

In one embodiment, Chapman describes hydrogenating a mixture of oxycodone and 14-hydroxycodeinone to prepare a mixture having less than 5 ppm of 14-hydroxycodeinone. Ex 2002, page 008, ¶ 0023.

Example 3 describes one method of implementing the Chapman invention. Ex 2002, pages 043-044, ¶¶ 0180-0187]

EXAMPLE 3

[0180] In Example 3, 27.83 g of oxycodone free-base, water wet (24.57 g dry basis, 0.0779 mol, ca. 3000 ppm 14-hydroxycodeinone), 39.8 g of deionized water, 81.9 g of isopropanol, 0.49 g 5% Pd/C [palladium on carbon] catalyst, 50% water wet Johnson Matthey type 87L), and conc. HCl [hydrochloric acid] (11.3 g, 0.117 mol, 1.50 equivalents based on 37.7% HCl assay) were combined in a 500 ml Parr shaker bottle.

[0181] The mixture was placed under an inert atmosphere and heated to 75° C. with

shaking. The pressure in the bottle was relieved, and the system was pressurized with hydrogen (45 PSIG). The solution was held under these conditions for 21.7 hours. Analysis by HPLC [high performance liquid chromatography] showed that the ratio of the area of the 8,14-dihydroxy-7,8-dihydrocodeinone peak to that of oxycodone was reduced from 0.29% to 0.04% during this time.

[0182] The hydrogen pressure was vented and the system was placed under an inert atmosphere. In order to prevent further dehydration of any residual 8,14-dihydroxy-7,8-dihydrocodeinone, the pH of the solution was adjusted from 0.5 to 1.8 with 20.7 g NaOH [sodium hydroxide] saturated isopropanol (some solid sodium hydroxide was also present).

[0183] The solution was re-heated to 75° C. and then pressure filtered through a 0.2 μm PTFE membrane filter housed in heat-traced 47 mm SS filter holder into a 500 ml jacketed cylindrical reactor (condenser, N2, mechanical stirrer, programmable refrigerated recirculator). The Parr bottle was rinsed with 8.6 g of deionized water, which was added to the flask through the filter.

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[0184] Isopropanol (222.5 g) was added to the solution in the flask and the resulting slurry was heated to approximately 75° C. to re-dissolve the solids. After reaching the desired temperature, the solution was held for two hours (to simulate typical processing times). No 14-hydroxycodeinone was detected in a sample of the crystallization mixture after this hold.

[0185] The circulator was set to cool from 80° C. to 0° C. over 8 hours. Approximately 24 hours after starting the cooling program, the solids were collected by suction filtration and washed three times with 95:5 isopropanol/water (232.8 g total). The material was dried as described in Example 1.

[0186] Analysis of the dried material using the low 14-hydroxycodeinone method of Example 4 below gave a result of 5 ppm of 14-hydroxycodeinone.

[0187] Analysis of the dried material using the method of Example 6 below gave a result of < 5ppm of codeinone and 10 ppm of 14-hydroxycodeinone.

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Chapman original claim 33 describes the following (Ex 2002, page 061):

> A process for preparing an oxycodone hydrochloride composition having a 14-hydroxycodeinone level in an amount of less than 25 ppm comprising reacting in a suitable solvent an oxycodone base composition having an amount of 8,14-dihydroxy-7,8-dihydrocodeinone; with hydrochloric acid in an amount greater than 1.0 molar equivalent as compared to the oxycodone base composition to promote the dehydration of the 8,14-dihydroxy-7,8-dihydrocodeinone to 14-hydroxycodeinone to form an oxycodone hydrochloride composition having a 14-hydroxycodeinone level in an amount of less than 25 ppm; the reacting step being performed under reducing conditions to promote the conversion of 14-hydroxycodeinone to oxycodone.

Chapman original claim 38 describes the process of claim 33 comprising hydrogenating the resultant oxycodone hydrochloride composition having 14-hydrocodeinone level in an amount of less than 25 ppm. Ex 2002, page 062.

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Marketplace demands

What marketplace demands were distributors of oxycodone facing in early 2004?

It appears that in the January 2004 time-frame, the FDA [Food and Drug Administration] may have been concerned about high levels of 14-hydroxycodeinone in oxycodone approved for use in the United States.

The first hint we have of the FDA's concern is testimony by Dr. Steven W. Baldwin, a witness for Chapman.

During cross-examination, Dr. Baldwin was asked whether he had an understanding of why there was a continuing need in the art to provide an oxycodone hydrochloride composition with reduced amounts of 14-hydroxycodeinone. Ex 1027, page 85:14-18.

According to Dr. Baldwin, the FDA wanted a commercial product that had lower amounts of the 14-hydroxycodeinone. Ex 1027, page 85:21-23.

Further cross-examination revealed that Dr. Baldwin gained his knowledge about FDA concerns from a conversation with Dr. Samuel S. Woodley, Esq., backup counsel for Chapman. Ex 1027, page 86:4-6.

Dr. Baldwin testified that Dr. Woodley had told Dr. Baldwin that the FDA told Purdue that it needed to decreased the amount of 14-hydroxycodeinone from its

product and that was the driving force behind finding a way to do that. Ex 1027, page 86:14-22.

The record also contains a Citizen Petition filed by Purdue Pharma L.P. with the FDA. Ex 2034.

The Purdue Citizen Petition requests that the FDA adopt, announce and implement a standard for the acceptable level of 14-hydroxycodeinone impurity in oxycodone HCl active ingredient approved by the FDA in use for drug products. Ex 2034, page 1 (Action Requested).

At some point, Purdue sought approval from the FDA to use oxycodone HCl active ingredient. Ex 2034, page 1 (Statement of Grounds).

According to Purdue, the FDA approval was contingent on successfully addressing the presence of 14-hydrocodeinone (an α,β-unsaturated ketone) impurity common to all commercial supplies of oxycodone HCl active ingredient. Id.

Specifically, in January of 2004, the FDA instructed Purdue to (1) provide extensive safety qualification data or (2) reduce the 14-hydrocodeinone level to not more than 10 parts per million (ppm). Ex 2034, page 002, first paragraph.

The representations in the Citizen Petition are consistent with statements in the Casner patent and the Chapman application.

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Casner says that "[r]ecently there has been a concern about the presence of α,β-unsaturated ketone impurities in pharmaceuticals and the Casner invention seeks to offer oxycodone having preferably below 10 ppm 14-hydroxcodeinone. Ex 2001, page 002, col. 1:65 through col. 2:6.

Likewise Chapman reveals that there is a need in the art to provide an oxycodone hydrochloride composition that contains reduced amounts of 14-hydroxycodeinone as compared to compositions known in the art.

To the extent that the need was a result of FDA directive in January of 2004 (Ex 2034, paragraph bridging pages 001-002), we note that on 30 March 2004, Purdue filed a provisional application containing Example 3 (reproduced above) describing a 14-hydrocodeinone content of 5 ppm. Ex 2008, page 035-36 (see last sentence of Example 3 on page 036).

On 23 September 2004, Casner filed a British patent application describing a method for making oxycodone with less than 5 ppm of 14-hydrocodeinone.

Of course it is possible that both Casner and Chapman were working on the known problem before the FDA directive in January of 2004.

However, based on the evidence—including the testimony, documents and statements in the specifications—we find that there was a commercial

need to reduce the amount of 14-hydrocodeine in oxycodone around the time Casner and Chapman made their inventions.

Both Casner and Chapman represent that they solved the commercial need. Ex 2002, pages 006-007, ¶ 0016; Ex 2001, page 002, col. 2:7-32.

Level of skill in the art

Dr. Gilbert Stork, a professor emeritus at Columbia University, testified on behalf of Casner. Ex 2004, page 4, ¶ 15.

Dr. Steven W. Baldwin, a professor at Duke University, testified on behalf of Chapman. Ex 1008, page 1, ¶ 2.

Both Dr. Stork and Dr. Baldwin have been awarded a Ph.D. in Chemistry and have worked extensively in the field of synthetic organic chemistry.

The invention involved in this interference falls within the scientific field of synthetic organic chemistry.

Both Dr. Stork and Dr. Baldwin are qualified as experts in the field of synthetic organic chemistry.

Accordingly, we find that both Dr. Stork and Dr. Baldwin are competent to give opinions in the field synthetic organic chemistry, the subject matter involved in this interference.

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Both Dr. Stork and Dr. Baldwin testified on level of skill of a hypothetical person skilled in the art involved in this interference.

As will become apparent, Dr. Stork's and Dr. Baldwin's views on the level of skill in the art went through a metamorphosis from (1) an early view for a need for a B.S. degree or equivalent training to (2) to an ultimate view for a need for a Ph.D. degree.

Since the testimony regarding the level of skill in the art was based on an evolving understanding of a hypothetical legal personality, we do not fault the metamorphosis in any respect.

Instead we commend the flexible manner in which both Dr. Stork and Dr. Baldwin adjusted their views in reaching their ultimate positions for the need for a Ph.D.

According to his direct declaration testimony, Dr. Stork expressed an opinion that a "skilled person" would have at least the equivalent of a Bachelor of Science degree in chemistry and will have had a least one year of laboratory experience either in academia or in industry. Ex 2004, page 008, ¶ 26.

On cross-examination when asked the basis for his opinion, Dr. Stork candidly acknowledged that that is what counsel for Casner had told him. Ex 2025, transcript page 18:22 through page 19:19.

Dr. Stork later clarified that the skilled person would be capable of following directions of a person working in the same laboratory, preferably in a pharmaceutical house. Ex 2025, transcript page 20:4-8; Ex 2025, transcript page 58:9-15.

Dr. Stork further clarified that the skilled person probably would have a Ph.D. Ex 2025, transcript page 24:20-24.

In his direct declaration testimony, Dr. Baldwin did not testify extensively as to the qualifications, as such, of a person having ordinary skill in the art.

However, Dr. Baldwin initially expressed an opinion that the steps involved in the "count" "involve only routine techniques that students with an undergraduate degree in chemistry or an equivalent level of education and training are able to perform. Ex 1008, page 27-28, ¶ 95. *See also* Ex 1008, page 22, ¶ 75.

On cross-examination (agreeing generally with Dr. Stork), Dr. Baldwin felt that a person with an undergraduate degree and some experience, working in a pharmaceutical company, would be able to perform the manipulations involved with direction from their supervisor, who of course, would have more training. *See generally* Ex 1027, page 72:25 through page 76:25.

Dr. Baldwin noted that (1) a supervisor typically would have at least a Ph.D. in synthetic organic chemistry and (2) it is the level of the supervisor—not a

technician —who is skilled in the synthetic chemistry art. Ex 1028, page 3, ¶¶ 9-10.

In general, we have no trouble agreeing with Dr. Stork and Dr. Baldwin that a person of ordinary skill in this art would have been awarded a Ph.D. degree and would have experience in synthetic organic chemistry.

The person would know how to research the scientific literature to gain knowledge concerning any particular synthetic chemical reaction.

The person would know that experimental work may be necessary to optimize result oriented variables.

Scope and content of the prior art

Oxycodone (Figure 1) can be made from thebaine (Figure 3).

When oxycodone is made from thebaine, a 14-hydroxycodeinone (Figure 2) by-product is produced.

As earlier noted, the presence of 14-hydroxycodeinone in commercially marketed oxycodone is not desirable.

Chapman, but not Casner, states in its specification that in addition to 14-hydroxycodeinone, another compound known as 8α,14-dihydroxy-7,8-dihydro-codeinone (Figure 4) is also produced when making oxycodone from thebaine. Ex 2002, page 006, ¶ 0013.

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Specifically, Chapman revealed in the Background of the Invention in its 2004 specification the following (Ex 2008, page 002, third paragraph—bracketed matter added):

> During the oxidation of thebaine to give 14-hydroxycodeinone [Figure 2], several overoxidized products are formed including [the impurity] 8,14-dihydroxy-7,8-dihydrocodeinone [Figure 4]. In the production of oxycodone free base from the 14 hydroxycodeinone, the 8,14-dihydroxy-7,8-dihydrocodeinone is carried through the process. During conversion of the oxycodone free base to oxycodone hydrochloride, the impurity undergoes acid-catalyzed dehydration and is converted into 14-hydro[xy]-codeinone. Thus, 14-hydroxycodeinone is present in the final oxycodone composition.

The parties are in disagreement whether the Chapman Background of the Invention is prior art.

Casner says yes and Chapman says no.

Here is what Chapman has to say (Chapman Opposition 9-10, Paper 48, page 1—citations to the record omitted and bracketed matter added):

> Chapman's invention was his [there are co-inventors] discovery of the source of that

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> 14-hydroxycodeinone and * * * how to remove it. Chapman discovered that when the * * * thebaine is converted by H_2O_2 [hydrogen peroxide] oxidation to the originally desired intermediate, 14-hydroxycodeinone, a contaminating by-product, 8,14-dihydroxy-7,8-dihydrocodeinone, is also formed. This contaminating 8,14-by-product" is unreacted when the original 14-hydroxycodeinone is hydrogenated to oxycodone. Rather, the 8,14-by-product is converted to new 14-hydroxycodeinone, when the oxycodone is reacted with hydrochloric acid to form a salt. The new 14-hydroxycodeinone is contaminating 14-hydroxycodeinone that Chapman's invention eliminates. No one before Chapman knew that contaminating 8,14-by-product was being formed and converted to new 14-hydroxycodeinone in the production of oxycodone HCL. Chapman's discovery lead to his method to convert the new 14-hydroxycodeinone to oxycodone using two well-known chemical reactions: [1] the acid catalyzed dehydration of β-hydroxyl carbonyl [*i.e.*, the 8,14-by-product (*see* Ex 2028, ¶ 28)] and [2] hydrogenation.

Casner's reply is that the prior art reveals that the information contained in the Background of the Invention was known—whether or not Chapman "independently" discovered that information. Casner Reply 9-10, Paper 57, page 1.

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Dr. Stork did a search on "SciFinder" and found Proksa, *10-Hydroxythebaine*, Arch. Pharm. Med. Chem. 369-70 (1999). Ex 2039, pages 12-13, ¶ 28.

As Dr. Stork explains, in 1999 Proksa described that the oxidation of thebaine with H_2O_2 [hydrogen peroxide] in the presence of a strong acid resulted in the formation of 14-hydroxycodeinone [Proksa Structure 2] as well other compounds including a compound identified as Proksa Structure 5. *Id.*

A person having ordinary skill in the art would have understood in 1999, and would understand today, that the Proksa compound having Structure 5 is 8,14-dihydroxy-7,8-dihydrocodeinone. *Id.*

It may be true that Chapman discovered independently from Proksa that when thebaine is converted by H_2O_2 [hydrogen peroxide] oxidation to the desired intermediate, 14-hydroxycodeinone, a contaminating by-product, 8,14-dihydroxy-7,8-dihydrocodeinone, is also formed.

However, Chapman's discovery that 8,14-dihydroxy-7,8-dihydrocodeinone is also formed was known in the prior art.

What is the significance of this prior art knowledge?

One skilled in the art would have understood—based on Proksa—that when step (a) of Chapman claim 96 calls for preparing a mixture of (i) oxycodone, (ii) solvent and

(iii) an acid what is being prepared is a mixture which comprises (1) oxycodone, (2) 14-hydroxycodeinone, (3) 8,14-dihydroxy-7,8-dihydrocodeinone, (4) a solvent and (5) an acid.

One skilled in the art also would have known that the 14-hydroxycodeinone is "removed" (via conversion to oxycodone) through a hydrogenation process. *See* (1) Ex 2016, Chiu, col. 11:51-60, Example 5 (col. 15) and col. 16:33-34; (2) Ex 2002, page 006, ¶ 0012 referring to a scientific article by Krabnig; and (3) Ex 1028, page 21, ¶ 60 [testimony of Dr. Baldwin]

Would one skilled in the art also have known how to "remove" the 8,14-dihydroxy-7,8-dihydrocodeinone?

Referring to Weiss, *Derivatives of Morphine. II. Demethylation of 14-hydroxycodeinone, 14-Hydroxymorphinone and 8,14-dihydroxydihydro-morphinone*, 22 J. Org. Chem. 1505-08 (1957) (Ex 2027), Dr. Stork testified that Weiss reveals that treatment with dilute HCl (1:1) in a boiling water bath for 20 minutes converted 8,14-dihydroxy-7,8-dihydrocodeinone into a compound having structure III. Ex 2031, page 010, ¶ 30; Ex 2027, page 1508 (sentence bridging cols. 1 and 2).

Dr. Stork further testified that one skilled in the art (*i.e.*, a synthetic organic chemist) would have understood that the compound having structure III (*see* page 1507 structure III which results when R = CH_3) is 14-hydroxycodeinone. Ex 2031, page 010, ¶ 30.

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Dr. Stork's testimony is consistent with his cross-examination where he stated that the "reaction, changing 8,14-dihydroxy[-7,8-dihydrocodeinone] into 14-hydro-codeinone, did exist in the literature before 2003 * * *." Ex 2025, transcript page 30:7-21.

On cross-examination, Dr. Stork also testified about other aspects of Weiss, but not about treatment of 8,14-dihydroxy-7,8-dihydrocodeinone being converted to 14-hydroxy-codeinone. Ex 2025, transcript page 202:4 through transcript page 204:23.

Referring to Iijima, *The Oxidation of Thebaine with m-Chloroperbenzoic Acid Studies in the (+)-Morphinan Series. III*, 60 Helvetica Chimica Acta, 2135-37 (1977) (Ex 2028), Dr. Stork observes that Iijima reports obtaining a compound having structure 5. Ex 2031, page 010, ¶ 33.

Dr. Stork testified that the compound having structure 5 (Ex 2028, page 2) would have been understood to correspond to 8,14-dihydroxy-7,8-dihydrocodeinone. Ex 2031, page 010, ¶ 33, last sentence.

Dr. Stork is of the opinion that if 8,14-dihydroxydihydro*thebaine* [not 8,14-dihydroxy, 7,8-dihydrocodeinone] is heated to 80° C. for 15 minutes in the presence of 5% hydrochloric acid [HCl], a *stable* (because it has a melting point) hydrochloride salt of 8,14-dihydroxy-7,8-dihydrocodeinone may exist. Ex 2031, pages 010-011, ¶¶ 34-35.

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Referring to Tada, *Ketalisation of α,β-Unsaturated Ketones, Part I 3-Methoxy-N-methylmorphinan Derivatives and 14-Hydroxycodeinone*, 22 Tetrahedron Letter, 1805-09 (1969) (Ex 2029), Dr. Stork notes that Compound 11 was obtained when Compound 7 was treated with 6N HCl [hydrochloric acid] at 100° C. for 3 hours. Ex 2031, page 011, ¶ 38.

Compound 7 would be understood by one skilled in the art to be 14-hydroxycodeinone. Ex 2031, page 011, ¶ 39.

Compound 11 would have been understood by one skilled in the art to be 8,14-dihydroxy-7,8-dihydrocodeinone. *Id.*

Dr. Stork's point seems to be that while some conditions result in 8,14-dihydroxy-7,8-dihydrocodeinone being converted to 14-dihydroxycodeinone (*e.g.*, Weiss), other conditions result in just the opposite (*e.g.*, Tada). Ex 2031, page 012, If 41.

Dr. Stork expressed the opinion that a person having ordinary skill in the art would understand that the pH, the temperature, and reaction time can each affect the compound or compounds produced from the combination of 8,14-dihydroxy-7,8-dihydrocodeinone and hydrochloric acid [HCl] in a solvent. Ex 2031, page 011, ¶ 37.

Weiss and Iijima support Dr. Stork's opinion.

Based on Tada, Dr. Stork expressed the view that greater specificity as to the particular reaction conditions, including the pH, time and temperature, is necessary to practice the 8,14-dihydroxy-7,8-dihydrocodeinone to 14-hydroxycodeinone reaction recited in what Dr. Stork refers to as Element IV of Chapman's claim 96. Ex 2031, page 012, ¶41.

Element IV is "incubating the mixture under conditions suitable to promote reaction of 8,14-dihydroxy-7,8-dihydrocodeinone to 14-hydro-xycodeinone." See Paper 48, Appendix 3.

Dr. Baldwin agrees with Dr. Stork that a person having ordinary skill in the art (e.g., a person with a Ph.D. and specializing in synthetic organic chemistry) would understand that the pH, the temperature, and reaction time can each affect the compound or compounds produced from the combination of 8,14-dihydroxy-7,8-dihydrocodeinone and hydrochloric acid [HCl] in a solvent.

Dr. Baldwin expressed the view that a person of ordinary skill would have no trouble identifying conditions suitable to promote reaction of 8,14-dihydroxy-7,8-dihydrocodeinone to 14-hydro-xycodeinone. Ex 1028, page 20, ¶ 55.

Referring to a standard text book (Ex 1029) and testimony by Dr. Stork, Dr. Baldwin explained that it was known that decreasing the pH of a reaction mixture promotes and accelerates dehydration. Ex 1028, page 20, ¶56.

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Referring to the same standard text book (Ex 1029) and testimony of Dr. Stork, Dr. Baldwin further explained that it was known that heat also promotes acid catalyzed dehydration reactions, of which conversion of 8,14-dihydroxy-7,8-dihydrocodeinone to 14-hydrocodeine is one example. Ex 1028, page 20, ¶ 57.

Dr. Baldwin still further explained that hydrogenation of 14-hydroxycodeinone to oxycodone was a traditional step in the synthesis of oxycodone before March 2004. Ex 1028, page 20, ¶ 59.

Differences

The principal differences between the "prior art" and the subject matter claims by Casner and Chapman is that no one reference describes all of the claimed process steps.

On the other hand each process step is generally known.

Furthermore, both Casner and Chapman use each step for its known purpose to achieve what one skilled in the art would have expected.

Level of skill in the art

As our findings make clear, both Dr. Stork initially expressed an opinion that a person skilled in the art had a relatively low skill level, *e.g.*, a B.S. degree and some lab experience (a technician in the lab).

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Dr. Stork's initial opinion was based on what he was told by counsel.

Dr. Baldwin had a similar initial opinion.

However, as they gained insight during cross-examination, both came to the view that the skilled person would have had a Ph.D. and would have had knowledge in synthetic organic chemistry.

What happened in this case is that while an initial "low" level was suggested by Dr. Stork and Dr. Baldwin, both came to an ultimate view that the skill level was quite "high."

In *DyStar Textilfarben GmbH. v. C.H. Patrick Co.*, 464 F.3d 1356, 1362-63 (Fed. Cir. 2006), the level of skill in the art was disputed.

The Federal Circuit held that the person of ordinary skill was not a "dyer" (as urged by one party) but a "person designing an optimal dyeing process" (as urged by the other party). 464 F.3d at 1363.

The person skilled in the art in the case before is not the "technician" in the lab taking direction from a supervisor; rather it is a synthetic organic chemist with considerable and sophisticated knowledge of (1) chemical reactions relevant to the field, (2) how to search the relevant literature and (3) how to accomplish complicated organic chemistry reactions in the relevant field.

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To the extent that there is any lingering view by either party that the person is a "technician" with a B.S. degree in chemistry, we would point out that such a view is inconsistent with prior art called to our attention by Dr. Stork and Dr. Baldwin.

We do not think that prior art can be ignored in the case before us anymore than the Brochet, Wimmer, and Chaumat prior art was implicitly ignored by the jury in *DyStar*. 464 F.3d at 1363.

Resolution of credibility

Dr. Stork and Dr. Baldwin, while agreeing on many points, disagree on significant points relevant to resolution of the factual and legal issues before us.

Based on a consideration of their direct testimony and cross-examination, *as a whole*, and because we feel that Dr. Baldwin's explanations are more persuasive and faithful to the content of the patent and application before us, as well as the prior art, we credit the testimony of Dr. Baldwin over that of Dr. Stork to the extent that their testimony is conflicting.

It is manifest that Dr. Baldwin has high respect for Dr. Stork ("professionally he's first rate, he's terrific and personally he's a great guy, very nice, very nice fellow") and that Dr. Stork is qualified to offer opinions in the field of synthetic organic chemistry. Ex 1027, page 15:5 through page 17:11.

It is also manifest that Dr. Stork has a high regard for Dr. Baldwin. Ex 2025, transcript page 208:8-12.

We wish to make clear that in making our credibility findings that we are confident that both Dr. Stork and Dr. Baldwin have candidly stated their respective opinions.

In our experience it is not unusual for highly qualified scientists to disagree on a point, particularly when the point involves application of what Dr. Stork legitimately characterized "legalese" (*e.g.*, the definition of a person having ordinary skill in the art). Ex 2025, transcript page 98:10-13 ("my knowledge of legalese was [understandably] not up to some of them").

Interference-in-fact

Casner moves for entry of a judgment of no interference-in-fact. Paper 28.

Casner does not deny that the subject matter of Casner claim 1 anticipates (35 U.S.C. § 102) the subject matter of Chapman claim 96.

Casner maintains, however, that the subject matter of Chapman claim 96 does not anticipate or render obvious (35 U.S.C. § 103) the subject matter of Casner claim 1.

The differences between the subject matter of Casner claim 1 and the subject matter of Chapman claim 96 are manifest from Appendix 3 of Casner Motion 1.

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APPENDIX 3
COMPARISON OF CASNER CLAIM 1 AND CHAPMAN CLAIM 96

Chart A		
Element	**Casner Claim 1**	**Chapman Claim 96**
I	A process for preparing oxycodone or an oxycodone salt, comprising the steps of:	A process for preparing oxycodone or an oxycodone salt, which process comprises steps of:
II	(a) preparing a mixture comprising oxycodone and a solvent,	(a) preparing a mixture of oxycodone, solvent,
III	adjusting the pH of the mixture to less than 6,	and an acid
IV	and heating the mixture	(b) incubating the mixture under conditions suitable to promote reaction of 8, 14-dihydroxy-7, 8-dihydrocodeinone to 14-hydroxycodeinone;
V	at the temperature of at least 55 °C	[Element not present]
VI	for a period of at least 1 hour;	[Element not present]
VII	and subsequently (b) exposing the mixture to hydrogenation reagents	and subsequently (c) exposing the mixture to hydrogenation reagents under conditions sufficient for conversion of 14-hydroxycodeinone to oxycodone.
VIII	for a period of at least 1 hour.	[Element not present]

Elements I and II in Casner Appendix 3 are present in both Casner claim 1 and Chapman claim 96.

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pH

Element III differs in that Casner adjusts the pH to less than 6 while Chapman adds an "acid" to the mixture of oxycodone and solvent.

Casner discloses that the pH is suitably adjusted by addition of a strong acid, such as concentrated hydrochloric acid, preferably at least one equivalent. The pH is to be adjusted to below 6 and can be adjusted to as low as 1.

Nothing critical is set out in Casner revealing that use of a pH higher than 6, but lower than 7, will not achieve (albeit perhaps inefficiently) the result sought be Casner. Ex 2001, page 002, col. 2:52-57.

The Casner patent does not explain why the pH has to be lower than 6.

Chapman Example 3 describes mixing *inter alia* oxycodone free-base and 1.50 equivalents of HCl (hydrochloric acid).

Dr. Baldwin agrees one cannot rigorously calculate the precise pH of the mixture described in Chapman Example 3.

Nevertheless we find convincing, Dr. Baldwin explanation why the pH in Chapman Example 3 would probably be in the 1-2 range.

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As Dr. Baldwin notes, there are 1.5 equivalents of HCl with no apparent base present to neutralize the acid effect of adding HCl. Ex 1027, page 98:10 through page 100:11.

Based on Dr. Baldwin's testimony, one skilled in the art would recognize that the pH in the first step of Example 3 is probably in the 1-2 range.

In any event, it is manifest that sufficient HCl has to be added to achieve a pH of less than 7 if one skilled in the art seeks to achieve Chapman's objective of obtaining an HCl salt of oxycodone.

Dr. Stork's testimony is that the pH would almost certainly be below 7 and depending on concentration of the acid, could be below 6. Ex 2004, page 010, ¶ 35; Ex 2025, transcript page 120:21 through page 121:13.

Dr. Stork apparently was not asked to explicitly comment on the presence of 1.5 equivalents of acid.

Incubation v. heating

Casner maintains that "incubating" (used in Chapman claim 96) and "heating" (used in Casner claim 1) are not the same thing.

Dr. Stork says "incubating" is not a term commonly used in the field of synthetic organic chemistry. Ex 2004, page 010, ¶ 39.

Dr. Stork goes on to say that "incubating" means maintaining a temperature and does not necessarily include heating the material to be incubated to that temperature. Ex 2004, page 011, ¶ 42.

Dr. Stork says that Chapman's use of the term "incubating" does not permit one skilled in the art to know the meets and bounds of Chapman claim 96. Ex 2004, page 011, ¶ 44.

Dr. Stork undertook no convincing analysis of the Chapman specification to see if it might shed some light on his understanding of "incubating."

Dr. Baldwin acknowledged that he typically does not use the terms "incubation" or "incubating" in his writings. Ex 1027, page 44:16 through page 45:2.

Nevertheless, Dr. Baldwin, referring to the Chapman specification, had no difficulty understanding that "incubating" was to be conducted to achieve a result set out in the Chapman specification. Ex 1008, ¶¶ 31-35.

As earlier mentioned, we have credited the testimony of Dr. Baldwin over that of Dr. Stork.

Dr. Baldwin's reference to and analysis of the Chapman specification and Dr. Stork's absence of a similar analysis is an example of why generally we credit Dr. Baldwin's testimony over that of Dr. Stork.

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Example 3 describes mixing ingredients and heating to 75° C. with shaking. Ex 2002, page 043, ¶ 0181.

Dr. Baldwin's analysis is consistent with Chapman Example 3.

In the context of the invention described by Chapman, we have no difficulty finding that "incubating" means maintaining a temperature to achieve the result set out in Chapman claim 96: promoting a stated reaction.

It seems rather apparent to us that, given the testimony and the nature of the Chapman invention, an incubating temperature is above room temperature that one has to "heat" before one can "incubate."

Temperature of 55° C for at least 1 hour

As Appendix 3, *supra*, reveals, Elements V and VI are not recited in involved Chapman claim 96.

Casner claim 1 requires that the mixture of Element II be heated to at least 55°C for a period of at least 1 hour.

Chapman claim 96 has no temperature or time period requirement.

Casner, of course, maintains that since Chapman claim 96 does not have the temperature and time limitation, the subject matter of Chapman claim 96

cannot render obvious the subject matter of Casner claim 1.

Step (b) of Chapman claim 96 says, however, that the "incubating" must occur "under conditions suitable" to promote a stated reaction.

Dr. Stork testified that "promote" has a variety of meanings. Ex 2004, page 011, ¶ 47.

On cross-examination, however, Dr. Stork acknowledged that an individual with a Ph.D. would know where to search the prior art literature to find the conditions necessary to accomplish the stated objective of Chapman's "incubating." Ex 2025, transcript page 30:6-21.

Dr. Baldwin recognized that the conditions had to be suitable to accomplish a stated objective. Ex 1008, ¶ 33-35.

On cross-examination, Dr. Baldwin was asked to elaborate on his views. Ex 1027, pages 101-110.

In particular, Dr. Baldwin discussed why the data in Chapman Example 3 describes a reported reduction of 8,14-dihydroxy-7,8-dihydrocodeinone from 0.29% to 0.04%. Ex 2002, page 043, ¶ 0181 and Ex 1027, page 103:25 through page 104:24.

Based on Dr. Baldwin's testimony, we find that the temperature and time conditions are result oriented

variables which one skilled in the art (someone with a Ph.D. with experience in synthetic organic chemistry) would be able to determine through routine experimentation.

Nothing in the Casner specification reveals why the claimed temperature and time period are critical, provided of course that the desired reaction takes place.

Hydrogenation for at least 1 hour

Casner Appendix reveals that Casner claim 1 requires hydrogenation for at least 1 hour while Chapman claim 96 is silent about the time needed for hydrogenation. *See* Element VIII.

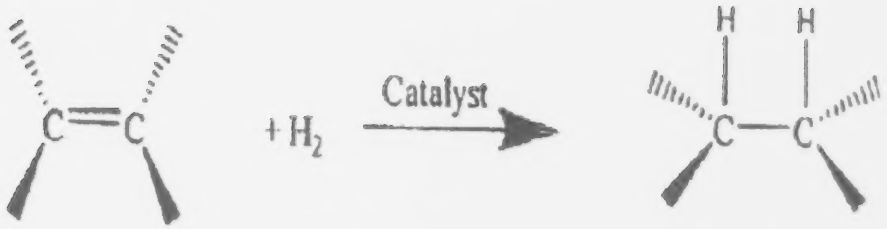
Casner also notes that in Element VII Chapman uses the "under conditions sufficient" language.

Dr. Stork testified that "conditions sufficient" has to take into account various reaction parameters, including temperature and pH, as well as time. Ex 2004, page 015, ¶ 55.

Casner claim 1 does not mention a hydrogenation temperature or the pH under which hydrogenation takes place.

Dr. Baldwin testified that hydrogenation is a term used by chemists and that a typical hydrogenation reaction is used to convert a double bond into a single bond consistent with the following general reaction scheme. Ex 1008, ¶¶ 37-38.

Appendix B



Hydrogenation reactions are fundamental to chemistry and are routinely taught in university curricula. Ex 1028, page 6, ¶¶ 15-16.

Dr. Baldwin testified about the conditions needed to accomplish hydrogenation.

As the reaction scheme reveals, hydrogen (*e.g.*, H_2) is needed. Ex 1008, ¶ 39.

A catalyst is also needed. Ex 1008, ¶ 40.

Dr. Baldwin testified that the Chapman application teaches the use of hydrogen and a catalyst. Ex 1008, ¶ 44.

On cross-examination, Dr. Baldwin elaborated. Ex 1027, page 66:21 through page 68:6.

Chapman Example 3 confirms the need for hydrogen ("pressurized with hydrogen") and a catalyst ("0.49 g 5% Pd/C catalyst"). Ex 2002, page 043, ¶¶ 0180-0181.

Appendix B

The "subsequently" limitation

Casner notes that Casner claim 1 requires "hydrogenation" to take place "subsequently" to Casner step (b), whereas Chapman claim 96 does not mention "subsequently."

Dr. Baldwin testified that he understood "subsequently" to mean that hydrogenation step (c) has to occur after step (b) is performed. Ex 1008, ¶ 47.

On cross-examination, Dr. Baldwin further testified that: "Until the dehydration [step (b)] has occurred hydrogenation will have no impact, and so for this whole process to work, we have to generate this double bond * * *", *i.e.*, the double bond between the 7- and 8-position of 14-dihydrocodeinone.

Once the "double bond is generated, then we can hydrogenate it." Ex 1027, page 58:18 through page 59:2.

Dr. Stork said essentially the same thing. Ex 2025, transcript page 86:22 through page 87:21.

In the context of this invention, the broadest reasonable construction of "subsequently" includes, but is not limited to, [1] completing step (b) by making all the 14-hydrocodeinone you are going to make, [2] stopping the making of 14-hydrocodeinone, and then [3] starting hydrogenating all of it to remove the double bond in 14-hydrocodeinone.

Rather, it means that hydrogenation must take place after dehydration of 8,14-dihydroxy-7,8-dihydrocodeinone to 14-hydroxycodeinone otherwise their would be no "dehydration" 14-hydroxycodeinone product to hydrogenate.

However, even if step (b) has to be completed before starting step (c), and assuming Chapman does not explicitly describe a stop/start process, one skilled in the art would find the difference insignificant because as Dr. Baldwin points out until you have 14-hydrocodeinone to hydrogenate, there is no reason to hydrogenate.

C. Casner Motions 9-10-obviousness

Legal principles

The legal principles application to the obviousness issues before us are straightforward.

A claimed invention is not patentable if the subject matter of the claimed invention would have been obvious to a person having ordinary skill in the art. 35 U.S.C. § 103(a); *KSR Int'l Co. v. TeleflEx Inc.*, 127 S. Ct. 1727 (2007); *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

Facts relevant to a determination of obviousness include (1) the scope and content of the prior art, (2) any differences between the claimed invention and the prior art, (3) the level of skill in the art and (4) any

relevant objective evidence of obviousness or non-obviousness. *KSR*, 127 S. Ct. at 1734; 1389, *Graham*, 383 U.S. at 17-18.

A person having ordinary skill in the art uses known elements and process steps for their intended purpose. *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57 (1969) (radiant-heat burner used for its intended purpose in combination with a spreader and a tamper and screed); *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282 (1976) (the involved patent simply arranges old elements with each performing the same function it had been known to perform); *Dunbar v. Myers*, 4 Otto (94 U.S.) 187, 195 (1876) (ordinary mechanics know how to use bolts, rivets and screws and it is obvious that any one knowing how to use such devices would know how to arrange a deflecting plate at one side of a circular saw which had such a device properly arranged on the other side); *DyStar Textilfarben GmbH. v. C.H. Patrick Co.*, 464 F.3d 1356, 1362-63 (Fed. Cir. 2006).

Chapman claim 96

Oxycodone has been made from thebaine. Ex 2002, page 005, ¶ 0006; Ex 2001, page 002, col. 1:65 through col. 2:6.

The FDA and the oxycodone industry recognized that there was a need to eliminate impurities in oxycodone.

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Those skilled in the art recognized that one known impurity in oxycodone made from thebaine was 14-hydroxycodeinone.

The Chapman background of the invention states, and Proksa confirms, that another known impurity was 8,14-dihydroxy-7,8-dihydrocodeinone. In view of Proksa, we need not resolve whether or not the Chapman background of the invention is prior art.

The 14-hydroxycodeinone impurity can be removed from oxycodone made from thebaine by a well-known hydrogenation process. Ex 2016, page 007, col. 11:46-60.

The hydrogenation process removes the double bond between the 7- and 8-positions.

However, since 8,14-dihydroxy-7,8-dihydrocodeinone impurity does not have a double bond between the 7- and 8-positions, one skilled in the art would have recognized that hydrogenation would not eliminate or reduce the amount of that impurity in oxycodone.

One skilled in the art, a synthetic organic chemist having at least a Ph.D. degree, would have known based on Weiss that appropriate treatment of 8,14-dihydroxy-7,8-dihydrocodeinone with hydrochloric acid would convert the 8,14-dihydroxy-7,8-dihydrocodeinone to 14-hydroxycodeinone.

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We will divert from a straightforward analysis at this point to address a concern raised by Dr. Stork, namely, that of making 14-hydroxycodeinone from 8,14-dihydroxy-7,8-dihydrocodeinone.

Based on Iijima and Tada, Dr. Stork expressed an opinion that the art is not predictable, that 8,14-dihydroxy-7,8-dihydrocodeinone may be a stable compound (Iijima), and that there are conditions under which treatment 14-hydroxycodeinone results in 8,14-dihydroxy-7,8-dihydrocodeinone (Tada).

We do not share Dr. Stork's concern, because one skilled in this art seeking to convert 8,14-dihydroxy-7,8-dihydrocodeinone to 14-hydrocodeinone would not use process conditions which do not accomplish the desired result.

Accordingly, one skilled in the art—while perhaps advised to be careful by Iijima and Tada—is going to use process conditions which achieve the desired result, those being shown by Weiss.

We agree instead with Dr. Baldwin's testimony that one skilled in the art would be able to identify the conditions suitable to promote reaction of 8,14-dihydroxy-7,8-dihydrocodeinone to 14-hydrocodeinone. Ex 1028, page 20, ¶ 55.

The facts in this case confirm the observation in *KSR* that "[a] person of ordinary skill is a person of ordinary creativity, not automaton." 127 S. Ct. at 1742.

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The person of ordinary skill in the art in this case is a highly sophisticated synthetic organic chemist who known how to search the literature and implement processes to achieve particular reactions. To that we would add that the person skilled in the art works in a highly competitive pharmaceutical industry. One skilled in the art in this case would have had a very high incentive to solve the problem identified by the FDA. The literature tells one skilled in the art how to do so.

Back to the analysis, one skilled in the art would have known that once the 8,14-dihydroxy-7,8-dihydrocodeinone is converted to 14-hydrocodeinone then hydrogenation would have converted most of the converted 14-hydrocodeinone to oxycodone.

Casner claim 1

Casner maintains that its involved claims are not unpatentable over the art it relies on to attack Chapman. We disagree.

The differences between Casner claim 1 and Chapman claim 96 are set out in Appendix 3 reproduced above.

What these differences amount to (1) use of a pH below 6, (2) a step (a) reaction temperature of at least 55°C for a period of at least 1 hour, and (3) hydrogenation for at least 1 hour.

In our view these differences do not make the subject matter of Casner claim 1 non-obvious over the prior art.

While Casner does not mention in its specification any problem associated with the presence of 8,14-dihydroxy-7,8-dihydrocodeinone impurity, the relevant literature, of which one skilled in the art would have been aware, reveals what needs to be done. To be sure, Casner does not have to actually know why its invention works—only that it does work. However, one skilled in the art aware of the literature called to our attention would immediately know why the Casner invention works—it works for the same reason that Chapman's invention works.

Back to the differences related to pH and reaction times and temperatures.

We will start with the proposition that one skilled in the art would have known that a pH would be necessary and that reactions times and temperatures would be necessary. The question is: "Would one skilled in the art know, or be able to figure out, what pH, reaction time and reaction temperatures to use?" In our view the answer, based on Dr. Baldwin's testimony—and in part on Dr. Stork's testimony—is "yes."

First, one skilled in the art would have known that reaction conditions affect the compound or compounds produced from the combination of 8,14-dihydroxy-7,8-dihydrocodeinone and hydrochloric acid. Dr. Stork seems to agree.

Second, dehydration is a well-known process. Dr. Baldwin convincingly told us that dehydration, along with hydrogenation, is a well known chemical process—processes which are taught in college chemical curricula and that hydrogenation is a traditional step in making oxycodone.

Third, when, as here, "there is a . . . market pressure to solve a problem and there are a finite number of identified, predictable solutions [determining pH and reaction times and temperatures], a person of ordinary skill has good reason to pursue the known options [dehydration and hydrogenation] within his or her technical grasp. If this leads to the anticipated success, [as did here,] it is likely the product not of innovation but of ordinary skill and common sense." *KSR*, 127 S. Ct. at 1742.

Fourth, there is no credible evidence before us which would make out a case that any unexpected result is achieved by use of the particular parameters ultimately described to be useful by Casner.

Based on the record before us, we hold that the subject matter of Chapman claim 96 and the subject matter of Casner claim 1 would have been obvious within the meaning of 35 U.S.C. § 103.

Appendix B

Chapman and Casner dependent claims

What about the dependent claims of the parties?

In presenting Casner Motions 9-10, Casner was under a burden to establish unpatentability of all of the Chapman claims, including the dependent claims. 37 C.F.R. § 41.121(b) (2007) and 37 C.F.R. § 41.207(b), last sentence (2007).

In its motion, Casner addresses all of Chapman's claims. Paper 32, pages 14-18.

In Chapman Oppositions 9-10, Chapman does not single out any of its dependent claims for separate consideration. Instead, Chapman bottoms its argument on Chapman claim 96.

In Casner Motions 9-10, Casner makes an attempt to establish that its claims are not unpatentable even if the Chapman claims are unpatentable. *See* 37 C.F.R. § 41.207(c) (2007). Paper 32, pages 18-20.

In Chapman Oppositions 9-10, Chapman expressed disagreement concerning the Casner dependent claims. Paper 48, pages 14-20.

In Casner Replies 9-10, Casner does not single out any dependent claim for separate consideration. Paper 57, pages 8-10.

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In this *inter partes* case, the parties have elected to argue the patentability of their respective dependent claims along with the patentability of Chapman claim 96 and Casner claim 1.

In view of the manner in which the case has been presented, in our view the dependent claims stand or fall together with Chapman claim 96 and Casner claim 1. We prefer to decide the contested issues rather than issues which might have been, but apparently for litigation reasons, were not contested. *Cf. Brand v. Miller*, 487 F.3d 862 (Fed. Cir. 2007).

The Eibel Process argument

Chapman attempts to convince us that the case is controlled by *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923). The inventor in *Eibel* solved an industrial problem of long-standing using a technique which a person skilled in the art would not have appreciated. It took many years for the inventor to solve a long-standing problem of trying to reach printing speeds of 500-600 feet per minute. The same is true of the invention found patentable in *Webster Loom Co. v. Higgins*, 15 Otto (105 U.S.) 580 (1881), where a loom was invented which would produce 50 yards of product per day when no one had been able to produce more than 40 yards per day. Here, on the other hand, the FDA and the pharmaceutical industry were faced with a problem which seems to have been solved in rather short order by those skilled in the art using their sophisticated skilled through application of known

techniques reported in the literature or which were otherwise known.

Conclusion of law

All the involved claims of both parties are unpatentable under 35 U.S.C. § 103 and a judgment against both parties is entered concurrently with this MEMORANDUM OPINION and ORDER.

D. Casner Motion 1-interference-in-fact

The underlying legal principles governing the motion are relatively simple.

An interference exists if the subject matter of a claim of one party (e.g., Casner claim 1) would, if prior art, have anticipated (35 U.S.C. § 102) or rendered obvious (35 U.S.C. § 103) the subject matter of a claim of the opposing party (e.g., Chapman claim 96) and vice versa. 37 C.F.R. § 41.203(a) (2007).

Casner, as movant, has the burden of proof on the issue of no interference-in-fact. 37 C.F.R. § 41.121(b) (2007).

Casner does not contest the fact that the subject matter of its claim 1 anticipates (35 U.S.C. § 102) the subject matter of Chapman claim 96.

Rather, Casner maintains that given differences between the subject matter of Chapman claim 96 and Casner claim 1 that the subject matter of Chapman claim 96 does not render obvious (35 U.S.C. § 103) the subject matter of Casner claim 1.

We disagree with Casner and deny Casner Motion 1.

Casner claim 1 is unpatentable over the prior art under 35 U.S.C. § 103.

When patentability under § 103 is considered in light of that art, and *the additional presumed prior art embodied in the subject matter of Chapman claim 96*, it is not difficult to see that Chapman and Casner are claiming the same "patentable" (perhaps "unpatentable" would be a better word) invention.

The scope and content of Chapman claim 96, when interpreted in light of the Chapman specification (including Example 3) appears in the findings.

Like the differences between Chapman claim 96 and Casner claim 1 appear in the findings.

There is not much we need to add to findings already made for the reader to understand why we believe Casner has failed to establish that the subject matter of Chapman claim 96 does not render obvious the subject matter of Casner claim 1.

While Chapman did not have the burden of proof, it has not gone unnoticed by that Dr. Baldwin's testimony more than establishes the obviousness of the subject matter of Casner claim 1 vis-à-vis Chapman claim 96 to a person having ordinary skill in the art.

Much of the Casner argument is about differences.

However, the mere existence of differences is not enough to render subject matter non-obvious under § 103. *Dann v. Johnston*, 425 U.S. 219, 230 (1976) [the mere existence of difference between the prior art (Chapman claim 96) and an invention (Casner claim 1) does not establish the invention's non-obviousness].

Dr. Baldwin has convincingly established why those differences do not overcome the § 103 hurdle in the context of a no interference-in-fact analysis.

Conclusion of law

Casner has failed to establish that there is no interference-in-fact.

E. Casner Motions 6-7—lack of written description/enablement

The legal principles applicable to a written description issue are set out in *In re Alton*, 76 F.3d 1168 (Fed. Cir. 1996), and need not be repeated here.

Appendix B

The legal principles applicable to an enablement issue are straightforward.

A specification must teach a person of ordinary skill in the art how to make and use the invention without resort to undue experimentation. *Enzo Biochem Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371-72 (Fed. Cir. 1999).

Factors which can be taken into account to determine whether undue experimentation is involved are set out in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988), adopting factors previously set out in *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. & Int. 1986).

The following observations by the Supreme Court are also applicable: the specification of the patent is not addressed to lawyers, or even to the public generally, but to those skilled in the art; and any description which is sufficient to apprise them in the language of the art of the definite feature of the invention, and to serve as a warning to others of what the patent claims as a monopoly, is sufficiently definite to sustain the patent and an inventor may assume that what was already known in the relevant art was known to those skilled in the art. *Carnegie Steel Co. v. Cambria Iron Co.*, 185 U.S. 403, __ (1902) (specification involving manufacturing of steel addressed to manufacturers of steel). *See also Webster Loom Co. v. Higgins*, 15 Otto (105 U.S.) 580, 586 (1881) (an inventor may begin a description of an invention at the point where his invention begins, and describe what he has made that is new, and what it replaces of the old; that which is common and known is

as if it were written out in the patent and delineated in the drawings).

Casner starts with the assertion that "incubation" is undefined. Dr. Baldwin explained otherwise and we are comfortable with Dr. Baldwin's explanation.

Arguing that conversion of 8,14-dihydroxy-7,8-dihydrocodeinone to 14-hydroxycodeinone would be dependent on a number of variable (including temperature, pH, and reaction times), Casner says the Chapman claims are unacceptable because those variables are not set out in the claims.

Dr. Baldwin and Dr. Stork acknowledged that one skilled in the art would know that those variables would need to be considered and Dr. Baldwin testified that one skilled in the art would be able to determine appropriate reaction temperatures, pH, and times.

We credit Dr. Baldwin's testimony.

Casner next attacks the language "under conditions suitable to promote dehydration."

However, the claim states the objective to be achieved and Dr. Baldwin testified that one skilled in the art would have been able to determine appropriate conditions.

Nor have we overlooked Chapman Example 3 which seems to provide a roadmap for carrying out the Chapman process.

Appendix B

The complaint Casner has with Example 3 is that while Chapman had possession of a temperature, Chapman did not have possession of a time of reaction.

Dr. Baldwin disagrees maintaining that one skilled in the art would have been able to determine an appropriate time.

Casner maintains that Chapman flunks *In re Wands.*

Dr. Baldwin disagrees.

We agree with Dr. Baldwin.

The fact that some search of the literature and some experimentation may be necessary is not *per se* sufficient to say any experimentation is "undue."

Casner has failed to establish that the experimentation which Dr. Baldwin found to be routine is "undue."

In addition to the points made by Dr. Baldwin, Example 3 and original claim 33 provide additional evidence that Chapman has a written description of the invention it now claims.

Appendix B

Conclusions of law

Casner has failed to establish that Chapman lacks a written description.

Casner has filed to establish that Chapman has failed to provide an enabling disclosure.

F. Other motions

The other motions before us seek earlier constructive reductions to practice or attack earlier constructive reductions to practice accorded in the declaration of the interference.

Since all the claims of the parties are unpatentable under 35 U.S.C. § 103, we see no occasion to reach the other motions.

They are dismissed as moot.

G. Observation on "objections" during cross-examination

During cross-examination, both parties often made an "Objection" without any brief reason in support of the objection.

The objections were technical violations of the Guidelines for Cross-examination.

We note that neither Dr. Stork nor Dr. Baldwin (much to their credit) seem to have been affected—hence we find there was no unwarranted witness coaching.

For further discussion and education, we call attention to *Pevarello v. Lan*, 85 USPQ2d 1771 (Bd. Pat. App. & Int. 2007).

H. Order

Upon consideration of the motions, and for the reasons given, it is

ORDERED that Chapman Motion 1 seeking an earlier constructive reduction to practice is *dismissed* as moot.

FURTHER ORDERED that Casner Motion 1 seeking judgment based on no interference-in-fact is *denied*.

FURTHER ORDERED that Casner Motion 2 attacking earlier constructive reductions to practice accorded to Chapman is *dismissed* as moot.

FURTHER ORDERED that Casner Motions 6-7 seeking judgment based on lack of written description and enablement is denied.

FURTHER ORDERED that Casner Motions 9-10 seeking judgment that the involved Chapman claims are unpatentable under 35 U.S.C. § 103 is *granted*.

FURTHER ORDERED that the involved Casner claims are also unpatentable under 35 U.S.C. § 103.

FURTHER ORDERED a judgment against both parties is entered concurrently herewith.

/ss/ Fred E. McKelvey
FRED E. McKELVEY
Senior Administrative
Patent Judge

/ss/ Richard Torczon
RICHARD TORCZON
Administrative Patent Judge

BOARD OF
PATENT
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AND
INTERFERENCES

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APPENDIX C — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DENYING PETITION FOR REHEARING FILED JUNE 15, 2009

2008-1427, -1428
(Interference No. 105,553)

ROBERT CHAPMAN, LONN S. RIDER, QI HONG, DONALD KYLE, and ROBERT KUPPER,

Appellants,

v.

MICHAEL LAWRENCE CASNER, JEN-SEN DUNG, ERNO M. KESKENY, and JIN LUO,

Cross Appellants.

Appeals from the United States Patent and Trademark Office, Board of Patent Appeals and Interferences.

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the Appellants, and a response thereto having been invited by the court and filed by the Cross-Appellants, and the petition for rehearing and response, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

Appendix C

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on June 22, 2009.

FOR THE COURT,

s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: 06/15/2009

APPENDIX D — JUDGMENT OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DATED MARCH 11, 2009

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2008-1427, -1428
(Interference No. 105,553)

ROBERT CHAPMAN, LONN S. RIDER, QI HONG, DONALD KYLE, and ROBERT KUPPER,

Appellants,

v.

MICHAEL LAWRENCE CASNER, JEN-SEN DUNG, ERNO M. KESKENY, and JIN LUO,

Cross-Appellants.

ON APPEAL from the United States Patent and Trademark Office, Board of Patent Appeals and Interferences

This CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

AFFIRMED.

Appendix D

ENTERED BY ORDER OF THE COURT

s/ Jan Horbaly/kw
Jan Horbaly, Clerk

DATED MAR 11 2009

ISSUED AS A MANDATE: JUN 22 2009

APPENDIX E — CHAPMAN CLEAN COPY OF INVOLVED CLAIMS DATED MAY 3, 2007

Paper No. _____
Dated filed: 03 May 2007

Filed on behalf of Chapman *et al.*
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UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

Interference 105,553 (McK)
Technology Center 1625

MICHAEL LAWRENCE **CASNER**, JEN-SEN DUNG, ERNO M. KENSKENY and JIN LUO,

Patent No. 7,153,966 B2,
Junior Party

v.

Appendix E

ROBERT **CHAPMAN,** LONN S. RIDER, QI HONG, DONALD KYLE and ROBERT KUPPER,

Application No. 11/391,897
Senior Party

CHAPMAN CLEAN COPY OF INVOLVED CLAIMS

Pursuant to the requirements of Bd. R. 110(a), the senior party Chapman *et al.* submits herewith, at Appendix 1 of this paper, a clean copy of its involved claims in this interference; *i.e.*, claims 96-118 of Application No. 11/391,897.

Dated, 03 May 2007

Respectfully submitted,

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Attachment: Appendix 1 - Clean Copy of Claims 96-118 of Chapman's Application No. 11/391,897

cc (by Federal Express overnight delivery):

RATNER & PRESTIA
(Attorney for Casner *et al.*)
1235 Westlak Drive, Suite 301
Berwyn, PA 19312

Appendix E

APPENDIX 1: CLEAN COPY OF CLAIMS 96-118 (*Of Chapman's Application No. 11/391,897*)

Claim 96: A process for preparing oxycodone or an oxycodone salt, which process comprises steps of:

(a) preparing a mixture of oxycodone, solvent and an acid;

(b) incubating the mixture under conditions suitable to promote reaction of 8,14-dihydroxy-7,8-dihydrocodeinone to 14-hydroxycodeinone; and subsequently

(c) exposing the mixture to hydrogenation reagents under conditions sufficient for conversion of 14-hydroxycodeinone to oxycodone.

Claim 97: The process according to claim 96, wherein in step (b) the mixture is heated to a temperature of about 75 °C.

Claim 98: The process according to claim 96, wherein the mixture has a pH of about 2.5 or less.

Claim 99: The process according to claim 98, wherein the mixture has a pH of about 1.8 or less.

Claim 100: The process according to claim 99, wherein the mixture has a pH of about 1.5 or less.

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Claim 101: The process according to claim 100, wherein the mixture has a pH of about 1 or less.

Claim 102: The process according to claim 96, wherein the hydrogenation reagents are a hydrogenation catalyst and either hydrogen or a hydrogen transfer reagent.

Claim 103: The process according to claim 96, wherein step (b) is carried out at a temperature between about 20 °C to about 100 °C.

Claim 104: The process according to claim 103, wherein step (b) is carried out at a temperature between about 40 °C to about 85 °C.

Claim 105: The process according to claim 96, wherein in step (c) the mixture is exposed to the hydrogenation reagents for between about 10 minutes to about 36 hours.

Claim 106: The process according to claim 105, wherein in step (c) the mixture is exposed to the hydrogenation reagents for at least about 4 hours.

Claim 107: The process according to claim 106, wherein in step (c) the mixture is exposed to the hydrogenation reagents for at least about 5 hours.

Claim 108: The process according to claim 107, wherein in step (c) the mixture is exposed to the hydrogenation reagents for about 21 hours.

Appendix E

Claim 109: The process according to claim 96, wherein the acid in said mixture is present in an amount greater than 1 molar equivalent compared to the amount of oxycodone.

Claim 110: The process according to claim 96, wherein the acid is hydrochloric acid.

Claim 111: The process according to claim 110, wherein the hydrochloric acid is present in an amount greater than 1 molar equivalent compared to the amount of oxycodone.

Claim 112: The process according to claim 111, wherein the hydrochloric acid is present in an amount greater than about 1.2 molar equivalents compared to the amount of oxycodone.

Claim 113: The process according to claim 112, wherein the hydrochloric acid is present in an amount greater than about 1.4 molar equivalents compared to the amount of oxycodone.

Claim 114: The process according to claim 113, wherein the hydrochloric acid is present in an amount greater than about 1.5 molar equivalents compared to the amount of oxycodone.

Claim 115: The process according to claim 96, wherein the resultant oxycodone contains 14-hydroxycodeinone in an amount less than about 25 parts per million ("ppm").

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Claim 116: The process according to claim 115, wherein the resultant oxycodone contains 14-hydroxycodeinone in an amount less than about 15 ppm.

Claim 117: The process according to claim 116, wherein the resultant oxycodone contains 14-hydroxycodeinone in an amount less than about 10 ppm.

Claim 118: The process according to claim 117, wherein the resultant oxycodone contains 14-hydroxycodeinone in an amount less than about 5 ppm.

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No. 09-320

IN THE

Supreme Court of the United States

ROBERT CHAPMAN, LONN S. RIDER, QI HONG, DONALD KYLE AND ROBERT KUPPER,

Petitioner,

v.

MICHAEL LAWRENCE CASNER, JEN-SEN DUNG, ERNO M. KESKENY AND JIN LUO,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF CENTER FOR ADVANCED STUDY AND RESEARCH ON INTELLECTUAL PROPERTY AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Whether an inventor who discovers the source of a problem may patent the solution even though the solution itself may be obvious once the source of the problem is discovered.

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INTEREST OF AMICUS CURIAE[1]

This case presents the question of whether an inventor who discovers the source of a problem may patent the solution even though the solution itself may be obvious once the source of the problem is discovered. Although this fundamental question of patent law arises in various technological contexts, it often arises, as it does here, in the context of fundamental scientific research discoveries that provide the basis for new pharmaceuticals.

Whether or not solutions derived from discoveries are protected by the patent laws is an issue of serious concern to *amicus curiae* Center for Advanced Study and Research on Intellectual Property ("CASRIP"), University of Washington School of Law. CASRIP is an independent research and policy development institute focusing on problems in patents and other property ownership rights in high technology. CASRIP was founded in the 1980s, and in 1992, CASRIP became part of the University of Washington School of Law. From its location at a nationally known research university, CASRIP works to assure that patent law promotes innovation. Thus, CASRIP regularly files *amicus curiae* briefs on patent law issues of importance to research universities.

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[1] Counsel of record for both parties received timely notice pursuant to Rule 37.2(a) of *amici curiae's* intention to file this brief, and the parties have consented to the filing. No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amicus curiae or its counsel made a monetary contribution to its preparation or submission.

The decision below is fundamentally at odds with the need of universities for legal protection of the practical results derived from their basic scientific research. The University of Washington and other research universities play a foundational role in the process of innovation that leads to life-saving and life-enhancing pharmaceutical products. The participation of universities in the drug development cycle has helped to make the United States a global leader in new drug development. For this cycle to function effectively, universities and other institutions involved in basic research must have legal protection for inventions that result from their discoveries. Because of CASRIP's unique role as an intellectual property law center based at a leading research university, CASRIP is well positioned to explain why review and reversal of the decision below is necessary to assure that basic scientific research continues to thrive.

REASONS FOR GRANTING THE WRIT

This case presents an issue of tremendous importance to all who conduct basic scientific research and all who benefit from basic research—i.e., everyone.

In the decision below, a divided panel of the Federal Circuit held that discovering a previously unnoticed compound that causes toxic impurities to form in oxycodone (a pain reliever) does not satisfy the "nonobviousness" requirement for patentability (35 U.S.C. § 103) even though the discovery led to a method for removing the impurities and improving the safety of oxycodone. Pet. App. 8a. Judge Rader dissented. Judge Rader noted that the scientist here, Robert Chapman, "was the first person to iden-

tify the true nature" of the high level of impurities of concern to the FDA in an approved pain reliever "and the first to solve it." Pet. App. 9a. In his view, "this important and innovative solution deserves a patent over the prior art." *Ibid.*

The decision below conflicts with precedent of this Court and of the Federal Circuit. The decision is in conflict with, for example, *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 68 (1923), which holds that a claim may be nonobvious when the inventor discovers a "source not before known" of a problem and then claims "application of the remedy" to solve the problem. Other recent Federal Circuit decisions have likewise held that a claim based on a discovery that leads to a new solution may be patentable. *See, e.g., Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358 (Fed. Cir. 2008).

The Federal Circuit's decision will hinder the development of new drugs and other useful products. Since 1980 and the passage of the Bayh-Dole Act, universities have held title to patented inventions that were developed by university scientists with federal funding. Universities, in turn, have licensed or otherwise transferred those patents to industry, which had the means and incentives to develop basic university research into commercial products. Unfortunately, the decision below threatens to return patent law to the pre-Bayh-Dole Act regime when practical results of basic scientific research were not brought to market.

I. THE DECISION BELOW CONFLICTS WITH DECISIONS OF THIS COURT AND THE FEDERAL CIRCUIT

"To promote the progress of science and the useful arts," the Constitution's Patent Clause authorizes Congress to secure for inventors the "exclusive right" to their "discoveries." U.S. Const. art. I, § 8. The decision below denies patent law protection to a meritorious discovery, and conflicts with the established precedent of this Court. The Federal Circuit is divided on the question presented.

A. The Decision Below Conflicts With The Precedent Of This Court

1. The decision below conflicts with *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923). There, the inventors claimed an improvement to a paper-making machine. When the prior art machines operated wires at speeds higher than 500 feet a minute, the machines made defective paper. The inventor, Eibel, discovered that the source of the defects were "disturbance and ripples in the [paper] stock" that arose at a point where the "wire was traveling much faster than the stock." *Id.* at 52. Eibel's solution was to increase the speed of the stock by taking advantage of gravity. The Court of Appeals invalidated the patent as an "obvious application of the principle that water will run down hill." *Ibid.*

In reversing and holding Eibel's claim permissible, this Court began by stating that "[t]he first and most important question is whether this was a real discovery of merit." *Id.* at 52. Noting that the discovery "surprised and startled the paper-making

trade" (and was soon copied), this Court found that "what he discovered and invented was new and useful." *Id.* at 55-56. This Court emphasized that "we must not lose sight of the fact that one essential part of [the inventor's] discovery was that the trouble causing the defective paper product under high machine speed was in the disturbance and ripples . . . due to the unequal speeds of stock and wire." *Id.* at 67-68. Thus, the invention "was not the mere use of a high or substantial pitch to remedy a known source of trouble." *Id.* at 68. Instead, it "was the discovery of the source not before known and the application of the remedy for which [the inventor] was entitled to be rewarded in his patent." *Ibid.*

The scientist here, Robert Chapman, is a modern-day Eibel. Just as Eibel set out to solve the problem of "disturbance and ripples," Chapman set out to solve the problem of impurities in a pain reliever (oxycodone). Just as the engineers paid no mind to the relative speed of the wire and stock in paper-making machines before Eibel, so to scientists unaware of the 8α by-product before Chapman. Just as Eibel discovered that the source of the problematic disturbance and ripples was the previously unremarked upon relative speed of wire and stock, Chapman discovered that the source of the problematic impurities was the previously unnoticed 8α by-product. Although both Eibel and Chapman used known methods to remedy the problem (gravity and hydrogenation), both Eibel and Chapman undeniably made "real discoveries of merit." As for Eibel, for Chapman it "was the discovery of the source not before known and the application of the remedy for which [he] was entitled to be rewarded in his pat-

ent." *Eibel*, 261 U.S. at 68.

The contrary Federal Circuit decision below contains the same erroneous analysis of the lower court in *Eibel*. Just as the *Eibel* lower court emphasized that the principle of gravity is well known, the court below emphasized that the use of hydrogenation to eliminate impurities was well known. Pet. App. 6a-7a. But it was not Chapman's application of the known hydrogenation step alone that warranted the patent; his discovery of the previously unknown presence of the 8α by-product, together with his proposed remedy, made his discovery one of "real merit."

In short, the decision below and *Eibel* are in conflict. *See* Pet. App. 9a-10a (Rader, J.) (discussing *Eibel*).

2. The decision below also is at odds with *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). There, this Court explained that the "bar on patents claiming obvious subject matter" is to assure that the "results of ordinary innovation are not the subject of exclusive rights under the patent laws." *Id.* at 398. "Were it otherwise patents might stifle, rather than promote, the progress of useful arts." *Ibid.* In particular, this Court further explained, when there is a need "to solve a problem and there are a finite number of identified predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." *Ibid.* "If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." *Ibid.*

Here, the majority's understanding of obvious-

ness cannot be reconciled with *KSR*. As Judge Rader explained, Chapman's claim based on an unexpected discovery is not "ordinary" innovation barred from patentability. Here, "there were no 'finite number of identified, predictable solutions' that were used to discover the source of and solution to the problems." Pet. App. 13a. "No persons of ordinary skill in the art knew of the existence of 8α before Chapman and, in fact, were trying to solve the problem of removing excess 14-hydroxy impurities from oxycodone salt by other means." *Ibid.* "Because no other persons had discovered and solved this problem as Chapman did, his invention is the product of innovation and not of 'ordinary skill and common sense.'" *Ibid.* By invoking the bar on obvious inventions to preclude patentability of a discovery of real merit, the majority's decision is at odds with with *KSR*.

B. The Federal Circuit Is Divided On The Question Presented

The divided decision below reflects a conflict at the Federal Circuit regarding whether a patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. As here, this unresolved disagreement often arises in disputes involving the claim to a pharmaceutically useful compound.

1. Judge Rader's dissent highlights three cases from the Court of Customs and Patent Appeals that emphasized the importance of protecting claims based on discovery of the source of a problem. Pet. App. 10a-12a, discussing *In re Conover*, 304 F.2d 680

(C.C.P.A. 1962); *In re Sponnoble*, 405 F.2d 578 (C.C.P.A. 1969); and *In re Application of Peehs*, 612 F.2d 1287 (C.C.P.A. 1980). In *Conover*, for example, the court stated: "It should not be necessary for this court to point out that a patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified." 405 F.2d at 585; *see also, e.g., In re Kaslow*, 707 F.2d 1366, 1373 (Fed. Cir. 1983) (the discovery of the source of a problem is a part of the Section 103 "subject matter as a whole" inquiry). As these prior decisions make clear, the inventive process may lead to a nonobvious solution to a known problem or, as here, it may lead to the identification of a nonobvious source of a problem that lends itself to a simple solution. Both of these processes may result in patentable inventions. Although the decision below places no weight on Chapman's discovery of the 8α by-product, under *Conover* and similar authority the unexpected discovery should have made the resulting claim patentable.

2. From the pharmaceutical context, Judge Rader relied (Pet. App. 13a-14a) on *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, 520 F.3d 1358 (Fed. Cir. 2008). There, at issue was a claim to an epilepsy drug (topiramate) that was formed during a search for new antidiabetic drugs. The scientist noticed that the compound had powerful anticonvulsant effects. The claim to the drug was challenged as obvious on the theory that a person faced with finding a new antidiabetic drug would have found topiramate. The Federal Circuit disagreed, emphasizing that the utility of the compound

(anticonvulsive activity) was not known in the prior art. Here, Judge Rader explained that under *Ortho-McNeil* Chapman's invention would be protected: "'The challenges of this inventive process would have prevented one of ordinary skill in this art from traversing the multiple obstacles to easily produce the invention in light of the evidence available at the time of the invention.'" Pet. App. 14a, quoting *Ortho-McNeil*.

II. THE FEDERAL CIRCUIT'S FAILURE TO PROTECT THE RESULTS OF SCIENTIFIC DISCOVERIES THREATENS THE DEVELOPMENT OF NEW DRUGS AND OTHER USEFUL PRODUCTS

The decision below threatens to reduce the public benefits gained from basic university research. The President's Council of Advisors on Science and Technology reported last year that universities are "a primary engine for discovery research that can lead to innovation."[2] The research conducted by universities usually focuses on fundamental questions, such as the sources of disease conditions.[3] Basic scientific research leads to useful innovation only if the patent laws protect the results of that research. Without patent protection, investors lack a critical mecha-

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[2] President's Council of Advisors on Science and Technology, *University-Private Sector Research Partnerships in the Innovation Ecosystem* 27 (2008) [hereinafter "President's Council"].

[3] *See, e.g.*, J.M. Hall et al., *Linkage of Early-Onset Familial Breast Cancer to Chromosome-17q21*, 250 Science 1684-89 (1990) (describing University of California scientists' discovery of the genetic cause of a common type of breast cancer).

nism for recovering the funds necessary to convert research into practical applications. Unfortunately, decisions like the one below ignore the practical necessity of patent protection.

A. Before The Bayh-Dole Act, Federally Funded University Research Rarely Led To New Drugs Or Other Useful Products

As the Constitution's Patent Clause reflects, the patent laws embody a "carefully crafted bargain" between public disclosure of an invention and the incentives necessary to promote innovation in the first place.[4] Although the fundamentals of the bargain between the inventor and the public are always the same, the details of how the public comes to benefit from an invention differ across industries. Because this case involves a method for generating a pharmaceutical compound, this section focuses on the pathway from basic research to subsequent new drug development.[5]

The process for bringing a new drug to market

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[4] *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-151 (1989).

[5] The information about the process for bringing a new drug to market, and the patent incentives that facilitate that process, is drawn from government and industry reports. *See generally* PhRMA, *Drug Discovery and Development: Understanding the R&D Process* (2007); Cong. Budget Office, *Research and Development in the Pharmaceutical Industry* (2006); Gov't Accountability Office, *New Drug Development: Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts* (2006); Fed. Trade Comm'n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* Ch. 3 4-14 (2003).

involves five steps:

- Pre-discovery research — research to understand a disease and its causes.
- Discovery research — indentifying promising targets (i.e., pharmaceutical compounds) capable of treating diseases.
- Preclinical testing — testing in labs to predict whether the target is safe and effective.
- Clinical testing — testing in humans, which progresses from Phase 1 (safety testing on 20-100 people) to Phase 2 (effectiveness testing on 100-500 people) to Phase 3 (safety and effectiveness testing on 1,000-5,000 people).
- FDA review and approval.

The incentive of profits during the patent term is what drives pharmaceutical companies to navigate the complex and costly path of bringing a new drug to market. Pharmaceutical companies rely on the market exclusivity afforded by patents to recoup the significant amount of money invested to obtain FDA approval. Thus, for example, drug companies are not permitted to introduce generic drugs until sufficient time has elapsed for the innovators—researchers and the pharmaceutical companies that turn that research into drugs—to realize a return on investment.[6]

Before 1980, pharmaceutical companies rarely

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[6] *See generally* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (1994)) (Hatch Waxman Act).

navigated the complex path of bringing drugs to market when the drug was based on federally funded university research. During this time, the United States held title to patented inventions developed by university scientists with federal funding. The United States did not effectively license or otherwise transfer those patented inventions to either universities or industry. Without rights to those patents and the market exclusivity they provide, industry had no incentive to undertake the costly development that is necessary to turn basic scientific research into commercially viable products.[7] Indeed, the gap between basic university research and subsequent commercialization was referred to as the "Valley of Death" because so much promising research failed to result in marketable products.

B. The Bayh-Dole Act Allowed Federally Funded University Research To Lead To New Drugs And Other Useful Products

In 1980, Congress passed the Bayh-Dole Act and established the following bargain: universities and others could privately own patented inventions that resulted from federal funding, but only if they took specific steps to promote subsequent development. 35 U.S.C. §§ 200-212. The Bayh-Dole Act encourages innovation by permitting the transfer of basic

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[7] Council on Governmental Relations, *The Bayh-Dole Act: A Guide to the Law and Implementing Regulations* 1-2 (1999) [hereinafter "Council on Governmental Relations"] (describing the history and purpose of the Bayh-Dole Act, including how "companies were reluctant to invest in and develop new products" because the government held title to patents).

scientific research from entities that do not have the infrastructure to turn that research into products (e.g., universities) to entities that do (e.g., pharmaceutical companies).[8]

In 2005, on the twenty-fifth anniversary of the Act, Congress passed a resolution lauding the Act's success: "the policies and objectives of the Bayh-Dole Act have been achieved and . . . the patent law has played a critical role in stimulating technological advances and disclosing useful technical information to the public." H.R. Con. Res. 319, 109th Cong. (2005) (enacted). For example:

- In 1980, fewer than 250 patents were issued to universities.[9] In 2007, 3,622 patents were

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[8] *See* Sean M. O'Connor, *Using Stock and Stock Options To Minimize Patent Royalty Payment Risks After* Medimmune v. Genentech, 3 NYU J. L. & Bus. 381, 449 (2007) ("[T]he Bayh-Dole Act was passed in large part to reduce the amount of innovative research being performed by universities and others under federal funding that was languishing 'on the shelf,' so to speak, because there was no clear, predictable mechanism to transfer the research results out to the public for commercialization.").

[9] AUTM, *U.S. Licensing Survey: FY 2004 Survey Summary* 2 (2005). The best data on university research comes from government reports and from the annual surveys of the Association of University Technology Managers ("AUTM"), a nonprofit organization that promotes technology transfer. AUTM was founded in 1974 and counts more than 300 universities and other research organizations as members. AUTM has surveyed its members every year since 1991. Respondents to AUTM surveys include research universities, hospitals, and research institutes.

issued to universities.[10]

- Since 1980, over 5,000 companies based on university research were formed. Those companies created over 260,000 jobs and are responsible for contributing over $40 billion annually to the American economy.[11]
- Between 1998 and 2005, more than 3,641 new products based on university research entered the marketplace.[12]

Dr. Richard B. Silverman, a professor of chemistry at Northwestern University, has described one example of federally funded basic research at a university leading to practical results.[13] During the 1980s and 1990s, Dr. Silverman and others conducted basic research into how enzymes assemble proteins, hormones, and other molecules. This research led to an identification of the source of neurological disorders and a better understanding of cer-

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[10] AUTM, *U.S. Licensing Survey, FY 2007 Survey Summary* 37-38 (2008) [hereinafter AUTM 2007 Survey].

[11] *The Bayh-Dole Act (P.L. 96-517, Amendments to the Patent and Trademark Act of 1980)—The Next 25 Years: Hearing Before the Subcomm. on Technology and Innovation of the H. Comm. on Science and Technology*, 110th Cong. 13 (July 17, 2007) (statement of Arundeep S. Pradham on behalf of AUTM).

[12] AUTM, *U.S. Licensing Survey, FY 2005 Survey Summary* 12 (2006).

[13] Richard B. Silverman, *From Basic Science to Blockbuster Drug. The Discovery of Lyrica*, Angewandte Chemie International Edition, 3500-3504 (2008). Additional information about Lyrica is available at AUTM, *U.S. Licensing Survey: FY 2006 Survey Summary* 22 (2007) and http://www.lyrica.com. Lyrica is protected by several patents.

tain neurotransmitters. This in turn led to the invention of a novel compound that treats pain, anxiety, epilepsy, and other maladies. Northwestern University licensed the patented compound to a pharmaceutical company that developed the drug Lyrica. In 2006, the first year after FDA approval, Lyrica had $1.2 billion in worldwide sales.[14]

In addition to bringing new drugs to market directly, the Bayh-Dole Act has also created other conditions that ultimately generate new drugs. Universities derive revenue from patents on basic research through licenses, equity positions in startups, and other means.[15] Moreover, since the Bayh-Dole Act, universities and industry have increasingly collaborated. Universities rely on this collaboration as a source of funding for about 5-7% of research in universities.[16] University-industry collaboration and technology transfer also aids universities by, among other benefits, aiding the flow of information be-

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[14] The Council on Governmental Relations has identified other similar results from the life sciences: an artificial lung surfactant for use with newborns, a platinum-based chemotherapy drug used to treat various types of cancers, a flu vaccine for the haemophilus influenzae type B, and an ophthalmic drop used for glaucoma. Council on Governmental Relations, at 8. Additional examples are identified in the yearly AUTM surveys, which provide vignettes of products originating from basic research at universities.

[15] For example, in 2008 The University of Washington received over $47 million in licensing revenue, a 23 percent increase from 2007. *See* UW TechTransfer, *FY 2008 Annual Report*, at 24 (http://depts.washington.edu/techtran/aboutus/Annual_Report/FY2008.pdf).

[16] Nat'l Sci. Found., *Science and Engineering Indicators* 2008 5-5 (2008) [hereinafter S&E Indicators 2008].

tween university and industry, providing practical research opportunities, connecting students with potential employers, enabling access to the industry's state-of-the-art equipment and knowledge, and many other benefits.[17]

Due to its success in the United States, the Bayh-Dole Act has been copied around the world, and versions of the Act are now in force in European (e.g., Belgium, Denmark, Germany) and Asian (e.g., India, Japan, Taiwan) countries.[18]

C. The Decision Below Threatens The Development Of New Drugs And Other New Products

In decisions like the one below, the Federal Circuit is in key respects returning patent law to its pre-Bayh-Dole Act days. By failing to provide patent protection for solutions based on the results of basic research, the Federal Circuit has established a regime whereby companies, including pharmaceutical companies, once again have insufficient incentives to

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[17] *See* National Council of University Research Administrators & National Research Institute, *Guiding Principles of University-Industry Endeavors* 6-7 (2006) (describing these and other benefits of university-industry collaborations).

[18] *See generally* Toshiko Takenaka, *Success or Failure? Japan's National Strategy on Intellectual Property and Evaluation of Its Impact from the Comparative Law Perspective*, 8 Wash. U. Global Studies L. Rev. 379, 384-86 (2009) (describing how Japan has enacted a patent system for universities that is similar to the Bayh-Dole Act); Benton C. Martin, *Comment: The American Models of Technology Transfer: Contextualized Emulation by Developing Countries?*, 6 Buff. Intell. Prop. L.J. 104 (2009) (describing technology transfer in universities and government research entities in the United States and around the world).

undertake the expensive process of turning basic research into marketable products.

In fact, the decision below resurrects the "Valley of Death" on an even wider scale. The decision applies to all basic research and is not limited to federally funded research. If discoveries of the sources of, for example, disease conditions that lead eventually to therapeutics, are not protected by the patent laws, fewer companies will take on the financial burden of converting such discoveries into marketable products. As the success of the Bayh-Dole Act proves, patent rights can be the difference between basic research discoveries that lead to no practical benefit and basic research discoveries that lead to new drugs and other useful products.

Other countries are not making the same mistake. European patent law, for example, provides that a patentable invention may be based on "a yet unrecognized problem to be solved (the solution being obvious once the problem is clearly stated)."[19] The European patent office guidelines illustrate this type of patentable invention with a case finding patentability despite "the claimed solution being retrospectively trivial and in itself obvious."[20] Although consistent with *Eibel*, European patent law provides greater protection to inventors than does the decision below.

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[19] EPO, *Guidelines for Examination in The European Patent Office*, Part C IV-24, 11.6 (2009).

[20] *Ibid.* (citing Decision of the Technical Board of Appeal, T2/83, OJ 6/1984, 265)).

Now is the time for the Court to review the Federal Circuit's failure to protect as patentable obvious solutions derived from a discovery of real merit. The President's Council has predicted that universities will perform an increasing amount of basic scientific research as industry is performing less.[21] By exempting from patent protection a whole class of inventions necessary to the development of new drugs and other new products, the decision below threatens to reduce the public benefits from scientific research for years to come.

III. THE QUESTION PRESENTED IS IMPORTANT TO THE UNITED STATES

The United States has three distinct interests in this matter.

First, the origins of this case lie in the government's desire that an approved pain reliever be made safer. Pet. App. 9a (Rader, J., dissenting) ("The Food and Drug Administration [("FDA")] seeks the removal of impurities such as 14-hydoxy from the pain medicine oxycodone salt."); *see also* Pet. App. 34a-36a (Board of Patent Appeals and Interferences) ("Specifically, in January of 2004, the FDA instructed Purdue [the owner of the Chapman patent] to (1) provide extensive safety qualification data or (2) reduce the 14-hydocodeinone level to not more than 10 parts per million (ppm)," citing Ex. 2034, page 002, first paragraph). The petition for certiorari and appendix do not further explain the FDA's role. The United States may be concerned that the Federal Circuit's decision will discourage scientists

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[21] President's Council at 5, 7, 17.

from addressing FDA safety concerns since the result of the safety research done here was not protected by patent law.

Second, the United States conducts basic scientific research and thus has a direct interest in the patent law scheme governing the solutions that result from basic discoveries. Congress passed the Stevenson-Wydler Technology Innovation Act of 1980 to promote the transfer of research from federal research entities to industry. 15 U.S.C. §§ 3701-14. As described by the National Institutes of Health, "[c]entral to both Stevenson-Wydler and Bayh-Dole was the concept of using the patent system as an incentive to private industry to participate in the further research and development needed to bring early-stage Federal innovations to practical application in the marketplace."[22] The decision below threatens the effort to bring federal research to "practical application" by eliminating the patent protection critical for marketing the results of federal research.

Third, the United States provides massive amounts of funding for basic research.[23] The United States funds about half of all research in the country. In 2007, the United States directly funded $137 billion worth of R&D. The United States funds $30

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[22] Nat'l Insts. of Health, *Report to Congress on Affordability of Inventions and Products* 4 (2004).

[23] Unless otherwise noted, the figures in this paragraph come from a recent report of the Congressional Budget Office. Cong. Budget Office, *Federal Support for Research and Development* i, 23-28 (2007).

billion (62%) of university research.[24] The United States also encourages research through tax incentives. In 2006, taxpayers claimed $9.9 billion in research and development tax incentives. These incentives include both the targeted research and experimentation tax credit and the general treatment of research and development spending as a fully deductible expense.[25] By denying patents for solutions to problems exposed by basic research discoveries, the decision below hampers the useful results that should follow from the United States' extensive funding of basic research.

In view of the United States' role and interests in this matter, the views of the Solicitor General may prove invaluable. *Cf.* SG Br. at 8 in *Merck KGAA v. Integra Lifesciences I, Ltd.*, 03-1237 (recommending review because "the court of appeals' decision poses a direct and substantial threat to new drug research"); *id.*, at 19 ("the affected federal agencies, including FDA and NIH, believe that the court of appeals' decision is likely to restrict significantly development of new drugs"); *id.* at 20 (ruling warrants review because it would "likely hinder the development of important and medically valuable new drugs").

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

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[24] Nat'l Sci. Found., *Academic Research and Development Expenditures: Fiscal Year 2007* 6 (2006).

[25] The research and experimentation tax credit was enacted pursuant to § 221 of the Economic Recovery Tax Act of 1981, 1981-2 C.B. 256, 293. It has been amended several times.

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